ALLEN RUBY (SBN 47109)
allen@allenruby.com
ALLEN RUBY, ATTORNEY AT LAW
15559 Union Ave. #138
Los Gatos, CA 95032
Telephone: (408) 477-9690

KAREN HOFFMAN LENT (*Pro Hac Vice*)
karen.lent@skadden.com
MICHAEL H. MENITOVE (*Pro Hac Vice*)
michael.menitove@skadden.com
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Telephone: (212) 735-3000
Facsimile: (212) 735-2040

MICHAEL S. BAILEY (*Pro Hac Vice*)
michael.bailey@skadden.com
SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Telephone: (202) 371-7000
Facsimile: (202) 393-5760

Attorneys for Defendant
INTUITIVE SURGICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff, v. INTUITIVE SURGICAL, INC., Defendant.	CASE NO.: 3:21-cv-03496-VC **DEFENDANT INTUITIVE SURGICAL, INC.'S ANSWER, AFFIRMATIVE DEFENSE AND COUNTERCLAIMS** Courtroom: 4 – 17th Floor Judge: The Honorable Vince Chhabria Complaint Filed: May 10, 2021

DEFENDANT'S ANSWER
AFFIRMATIVE DEFENSE AND COUNTERCLAIMS

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSE

Defendant Intuitive Surgical, Inc. ("Intuitive") hereby sets forth its Answer and Affirmative Defense to the Complaint ("Complaint") filed by Plaintiff Surgical Instrument Service Company, Inc. ("SIS"). Except as otherwise expressly set forth below, Intuitive denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint. Any allegation, averment, contention or statement in the Complaint not specifically and unequivocally admitted is denied, including any statement in a heading. Intuitive preserves all objections regarding the admissibility of any allegations or statements made in the Complaint or in this Answer and Affirmative Defense. Intuitive responds to each of the paragraphs of the Complaint as follows:

RESPONSE TO "INTRODUCTION"

Paragraph 1: SIS has 50 years of experience servicing surgical instruments and equipment ranging from simple devices such as forceps and scalpels to complex electromechanical devices such as flexible video endoscopes, powered orthopedic devices, and surgical video systems. SIS employs exhaustive inspection and repair procedures to ensure that previously used surgical instruments are only returned to the operating room in accordance with specifications. SIS's services save health care providers and patients millions of dollars a year, reducing the per-surgery cost of procedures without compromising instrument operation or patient safety. SIS is a trusted nationwide partner for hospitals, health care systems, and group purchasing organizations ("GPOs"), including in this District

1. Intuitive denies the allegations in paragraph 1 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 2: Since the late 1990's, defendant Intuitive has been the leading provider of robotic surgery systems for minimally invasive soft tissue surgeries. In contrast to operating directly on a patient, the surgeon using Intuitive's system remotely operates a multi-arm "da Vinci" surgical robot from a console that receives video of the surgical site and includes means for precisely controlling the movement and operation of surgical tools known as EndoWrists. EndoWrists include traditional surgical tools such as forceps and scalpels and are attached to the robotic arms based on the type of surgery to be performed. The robotic arms include motors that control cables within the EndoWrist in response to the surgeon's inputs, allowing precise multi-axis movement of the "wrist" of the surgical tool that is not possible in traditional surgeries.

2. Intuitive admits that it has been a provider of robotic-assisted surgical systems for minimally invasive soft tissue surgeries since the 1990s. Intuitive admits that the surgeon using Intuitive's robotic-assisted surgical system, known as a da Vinci Surgical System ("da Vinci"), operates a multi-arm system from a console that receives video of the surgical site and includes means for precisely controlling the movement and operation of surgical tools, many of which incorporate EndoWrist technology. Intuitive admits that surgical instruments that have EndoWrist technology are called "EndoWrists," some of which include forceps and scalpels and are attached to da Vinci robotic arms based on the type of surgery to be performed. Intuitive admits that the robotic arms include motors that control cables within the EndoWrist in response to the surgeon's inputs, allowing precise multi-axis movement of the "wrist" of the surgical tool that is not possible in all types of surgeries based on the type of surgery to be performed. Intuitive otherwise denies the allegations in paragraph 2.

Paragraph 3: Intuitive has monopoly power in the relevant markets of surgical robots for minimally invasive surgeries, the instruments used in such surgeries, and the servicing of those surgical robots, with a 99%+ market share. In the early 2000's, Intuitive's Form 10-K filings noted a use counter to limit the number of operations performed with EndoWrist instruments, and acknowledged its strategy to "sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis." As Intuitive has since gained and exercised monopoly power in the relevant markets, this strategy has become extremely profitable. Although revenue from the da Vinci robots initially exceeded revenue from instrument and accessory sales, by fiscal year 2013 Intuitive's revenues from instruments and accessories surpassed da Vinci robot revenue. By fiscal year 2019 instrument and accessories revenue exceeded $2.4 billion, or more than a $1 billion more than sales of da Vinci systems. Although Intuitive does not break out its gross profit for instruments alone, its gross profit on instruments and da Vinci systems is over 70%.

3. Intuitive admits that its 10-K for the year ended December 31, 2000 stated that Intuitive "can sell the instruments for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure basis or per-hour basis," but otherwise denies the allegations in the second sentence of paragraph 3. Intuitive admits that revenue from sales of da Vincis initially exceeded revenue from instrument and accessory sales, and by fiscal year 2013,

Intuitive's revenues from instruments and accessories surpassed revenue from da Vinci sales, but otherwise denies the allegations in the fourth sentence of paragraph 3. Intuitive admits that in fiscal year 2019, instrument and accessories revenue exceeded $2.4 billion, and sales of da Vincis were more than $1 billion, but otherwise denies the allegations in the fifth sentence of paragraph 3. Intuitive admits that its gross profit on instruments and da Vincis is 70.2% of product revenue, but otherwise denies the allegations in the sixth sentence of paragraph 3. Intuitive denies the allegations in the first and third sentences of paragraph 3.

Paragraph 4: In connection with the purchase or lease of da Vinci Surgical products, Intuitive requires customers to enter into a Terms and Conditions Agreement ("Sales Agreement") and a Use, License and Service Agreement ("ULSA"). In connection with the agreements required to purchase or lease an Intuitive robotic Surgical System, Intuitive demands that customers further agree to a limited license for the use of EndoWrist instruments. The limited license expires once an EndoWrist instrument is used up to its maximum number of uses as specified in the documentation accompanying the particular instrument. Intuitive's ULSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrist instruments, whether before or after the limited use license has expired. Further, if a customer has or attempts to have an EndoWrist instrument repaired, refurbished or reconditioned, Intuitive has threatened to terminate the entire Use, License and Service Agreement with the customer immediately upon written notice, and any warranties applicable to the da Vinci robotic Surgical System will become void. Intuitive has advised its customers that should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at a customer's site for a service call, that the da Vinci robotic Surgical System has been used with EndoWrist instruments refurbished or modified by any unauthorized third party, Intuitive will no longer provide any service for the customer's entire robotic system.

4. Intuitive admits that customers enter into a "Sales, License and Service Agreement" ("SLSA") with Intuitive when they purchase or lease a da Vinci and that through this agreement customers agree to a limited license for the use of EndoWrists, but otherwise denies the allegations in the first and second sentences of paragraph 4. Intuitive admits that the limited license to use an EndoWrist expires once the instrument is used up to its maximum number of uses as specified in the documentation accompanying the particular instrument, but otherwise denies the allegations in the third sentence of paragraph 4. Intuitive admits that the

SLSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrists at any time, but otherwise denies the allegations in the fourth sentence of paragraph 4. Intuitive admits that it has informed customers of their contractual obligations and safety concerns related to the use of unauthorized third parties to repair, refurbish or recondition EndoWrists, but otherwise denies the allegations in the fifth and sixth sentences of paragraph 4.

Paragraph 5: Plaintiff SIS has detailed procedures for servicing used EndoWrists to original specifications and returning them to service. These procedures include disassembly of the EndoWrist, inspection of all components, adjustment of components as necessary, confirming all movements, and setting a counter to Intuitive's original counter value. While these procedures are extensive and return the EndoWrist to original performance specifications, the cost to the hospital is a fraction of what Intuitive charges to buy a new EndoWrist. In 2019 and 2020, SIS entered into contracts and was in discussion for other contracts to provide EndoWrist repair services to numerous hospitals, health care systems, and GPOs. The cost savings were so substantial that one of the nation's largest health care systems awarded SIS's EndoWrist repair program a prestigious annual award for cost savings. Revenues for SIS, and savings to hospitals and patients, were anticipated to be in the tens if not hundreds of millions of dollars.

5. Intuitive denies the allegations in the first, second, fourth, fifth and sixth sentences of paragraph 5 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 5.

Paragraph 6: When Intuitive discovered that its customers were using SIS's services, it immediately leveraged its anti-competitive agreements and monopoly power to crush this threat to its supra-competitive EndoWrist profitability. Intuitive's agreements with hospitals include numerous restrictive terms that allow Intuitive to render the da Vinci robots effectively inoperable, and it threatened to exercise those terms against hospitals that used SIS's services. Intuitive also made misleading statements that use of refurbished EndoWrists would violate FDA requirements and intellectual property rights.

6. Intuitive denies the allegations in paragraph 6.

Paragraph 7: Despite the massive savings to hospitals and patients from SIS's EndoWrist program, SIS's customers and potential customers had no choice but to capitulate to Intuitive's threats. Because of Intuitive's monopoly power in minimally invasive surgical robots, the instruments for those robots, and the servicing of those robots, there are no realistic alternative suppliers in those relevant markets. Health care providers have made massive capital investments in da Vinci robots, surgeons are specifically trained to perform surgery with those

robots, and a large number of patients choose da Vinci robotic surgeries despite a significantly higher out-of-pocket cost. To lose access to existing da Vinci robots would not only waste an expensive capital investment, but would effectively foreclose hospitals and surgeons from performing certain types of surgeries.

7. Intuitive denies the allegations in paragraph 7.

Paragraph 8: Intuitive's anti-competitive conduct cannot be justified by any purported safety or regulatory requirements. All components of the EndoWrists are medical-grade materials that are capable of many times more uses than permitted by Intuitive's unilaterally programmed counter. SIS's services ensure that the inspected or repaired EndoWrists meet all original specifications, and SIS sets the instrument counter to the original value provided by Intuitive. In sum, the only purpose of Intuitive's anti-competitive conduct is to maintain supra-competitive "per-procedure" EndoWrist pricing. By leveraging its monopoly power and anti-competitive agreements in this manner, Intuitive has violated the Sherman Act's prohibitions on monopoly, attempted monopoly, exclusive dealing and tying, and the Lanham Act's prohibition on unfair competition.

8. Intuitive denies the allegations in third sentence of paragraph 8 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the first, second, fourth and fifth sentences of paragraph 8.

Paragraph 9: Intuitive is the dominant supplier of robotic Surgical Systems for minimally invasive soft tissue surgeries. Intuitive essentially has no competition in this market. Additionally, Intuitive is the dominant supplier of instruments used with minimally invasive soft tissue robots and the dominant supplier of servicing for the robots — essentially having no competition in either of these markets as well.

9. Intuitive denies the allegations in paragraph 9.

Paragraph 10: Intuitive has used its monopoly power in the EndoWrist instrument replacement aftermarket, as well as in the servicing of surgical robots, to engage in a variety of anticompetitive practices. These exclusionary practices essentially prevent hospitals, health care systems, and GPO's from having access to competitors that offer to repair and refurbish EndoWrist instruments which have been previously used.

10. Intuitive denies the allegations in paragraph 10.

Paragraph 11: Intuitive wields its monopoly power in the market for robotic soft tissue surgery systems to coerce hospitals, health care systems, and GPO's to act in ways that have anticompetitive effects thus harming competition. Such coercion is backed up by Intuitive's threats to withhold technical support and servicing for the robotic surgery systems purchased by hospitals, health care systems, and GPO's and to deny those customers access to additional

and/or replacement EndoWrist instruments.

11. Intuitive denies the allegations in paragraph 11.

RESPONSE TO "PARTIES"

Paragraph 12: Plaintiff Surgical Instrument Service Company, Inc. is an Illinois corporation with a principal place of business at 151 N. Brandon Drive, Glendale Heights, Illinois.

12. Intuitive denies the allegations in paragraph 12 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 13: Defendant Intuitive Surgical, Inc. is a Delaware corporation with a principal place of business at 1020 Kifer Road, Sunnyvale, California.

13. Intuitive admits that it is a Delaware corporation with its executive offices at 1020 Kifer Road, Sunnyvale, California, but otherwise denies the allegations in paragraph 13.

RESPONSE TO "JURISDICTION AND VENUE"

Paragraph 14: Jurisdiction - This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 22, and 1121. Defendant has been engaged in interstate commerce during all relevant times of the Complaint.

14. Intuitive admits the allegations in paragraph 14.

Paragraph 15: Jurisdiction - This Court has personal jurisdiction over Defendant due to its business activities in this District, including Defendant being headquartered in this District.

15. Intuitive admits the allegations in paragraph 15.

Paragraph 16: Venue is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). Intuitive is headquartered in this District and a substantial part of the events giving rise to all claims occurred in this District.

16. Intuitive admits that venue is proper and that it transacts business in this district, but otherwise denies the allegations in paragraph 16.

Paragraph 17: Intradistrict Assignment – Pursuant to Civil L.R. 3-2(c), the present action is an antitrust action that is assigned on a district-wide basis.

17. Intuitive admits the allegations in paragraph 17.

RESPONSE TO "I. SIS'S SURGICAL INSTRUMENT REPAIR BUSINESS"

Paragraph 18: Founded in 1971, SIS has been a leader in surgical instrument and equipment service and repair for 50 years. During this time, SIS has safely and effectively serviced millions of surgical instruments for health care providers. SIS's best-in-class team, equipment, and processes are trusted by hundreds of hospitals throughout the country, including hospitals in this District. SIS does not merely inspect and repair surgical instruments, but also functions as an operational partner for its client hospitals, improving their operations and processes.

18. Intuitive denies the allegations in paragraph 18 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 19: SIS services a wide variety of instruments, ranging from relatively simple mechanical devices such as traditional standard and laparoscopic instruments to complex instruments such as electrical and pneumatic saws and drills, a wide range of optical and video endoscopes, and surgical video equipment. Based on the FDA's Quality Systems Regulation (QSR) and current Good Manufacturing Practices (cGMP), SIS develops inspection and repair processes that ensure that any equipment returned to the hospital or surgical field will function properly.

19. Intuitive denies the allegations in paragraph 19 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 20: Based on this extensive experience with a wide range of surgical instruments, SIS is intimately familiar with the capabilities and lifespan of medical grade materials and components such as stainless steel, composites, and tungsten used in such devices. SIS technicians employ industry-leading procedures for inspection, alignment, sharpening, electrical insulation test, and additional necessary steps to return instruments to the field with confidence. Instruments that are regularly serviced by SIS are capable of dozens, hundreds, or thousands of uses over their lifetime, depending on the type of equipment and materials.

20. Intuitive denies the allegations in paragraph 20 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 21: SIS's services, and those like it, are essential to the safe and cost-effective operation of hospitals throughout the country. SIS's preventative maintenance and inspection services ensure that instruments used in medical procedures and surgeries are safe. Its repair services substantially extend the life of surgical instruments, resulting in substantial savings for health care providers and patients.

21. Intuitive denies the allegations in paragraph 21 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

RESPONSE TO "II. INTUITIVE'S DA VINCI SURGICAL ROBOTS AND ENDOWRISTS"

Paragraph 22: For over 20 years, Intuitive has developed and sold the "da Vinci" line of minimally invasive surgical robot systems. A previous generation of da Vinci surgical robots that is currently being phased out is called the "Si," while the most recent "Xi" version was launched in 2014. Additional versions of these systems also exist under the X and SP monikers. Collectively, there are over 3,500 da Vinci robotic surgery systems employed by United States hospitals and surgery centers, and over 5,500 worldwide.

22. Intuitive admits that it has developed and sold da Vincis used in robotic-assisted surgery for over 20 years, but otherwise denies the allegations in the first sentence of paragraph 22. Intuitive admits that it has developed and sold different generations of da Vincis, including the da Vinci Si, da Vinci Xi, da Vinci X and da Vinci SP, and is currently phasing out the da Vinci Si, but otherwise denies the allegations in the second and third sentences of paragraph 22. Intuitive admits that at the end of 2020, Intuitive had an installed base of 5,989 da Vincis worldwide, including 3,720 in the United States, but otherwise denies the allegations in the fourth sentence of paragraph 22.

Paragraph 23: The da Vinci system generally includes a multi-arm surgical robot (left), surgeon's console (center), and a vision cart (right): [images]

23. Intuitive admits that the images in paragraph 23 show a multi-arm surgical system (left), surgeon's console (center), and a vision cart (right), but otherwise denies the allegations in paragraph 23.

Paragraph 24: A new da Vinci system, including the surgical robot vision cart, typically costs more than $2.0 million. Although Intuitive has begun leasing the da Vinci system to some customers, the vast majority (> 85%) of active da Vinci systems are purchased by hospitals as capital equipment.

24. Intuitive admits that the da Vinci generally sells for between $500,000 and $2.5 million, depending upon the model, configuration and geography, but otherwise denies the allegations in the first sentence of paragraph 24. Intuitive admits that during the year ended

December 31, 2020, Intuitive had a total of 901 da Vincis installed at customers under operating lease or usage-based arrangements, accounting for approximately 15% of Intuitive's total installed base worldwide, but otherwise denies the allegations in the second sentence of paragraph 24.

Paragraph 25: The instruments used in the surgical procedure are attached to the arms of the surgical robot, and the surgical robot is positioned relative to the target surgical region of the patient. All of the 80+ instruments used with da Vinci robots are supplied by Intuitive under its EndoWrist brand. EndoWrist instruments are the only FDA-approved instruments for use with the da Vinci systems.

25. Intuitive admits that surgical instruments are attached to the da Vinci and that it is positioned relative to the target surgical region of the patient, but otherwise denies the allegations in the first sentence of paragraph 25. Intuitive admits that it sells more than 80 different EndoWrists used with da Vincis that have received FDA clearance, but otherwise denies the allegations in the second and third sentences of paragraph 25.

Paragraph 26: In a typical procedure, a number of small incisions are made to provide the EndoWrist surgical instruments access to the target surgical region. A camera provides high-definition 3D images to the surgeon at the surgeon's console and to other operating room personnel via a large screen of the vision cart. The surgeon directs the surgery by manipulating controllers on the console, which allow for precision control of the robot arms and EndoWrist instruments. This allows the surgeon to specify movements on a scale that is at least an order of magnitude less than the surgeon's actual hand movements at the console.

26. Intuitive admits that one form of robotic-assisted surgery uses several incisions for the insertion of small tools, including a magnified, high-definition 3D video camera that shows images to the surgeons and other operating room personnel via a large screen of the vision cart, and that the surgeon may sit at the surgeon's console and use hand controls to manipulate the instruments, which are attached to the system by robotic arms with joints, but otherwise denies the allegations in the first, second and third sentences of paragraph 26. Intuitive admits that the movements of a surgeon using a da Vinci are scaled, but otherwise denies the allegations

in the fourth sentence of paragraph 26.

Paragraph 27: The surgical instruments located at the end of the EndoWrists, such as scalpels, clamps, forceps, scissors, and needle drivers, are substantially identical to similar instruments used in traditional surgeries. In fact, Intuitive reported to the FDA that EndoWrists and traditional surgical instruments "are essentially identical... in terms of shape, size, function, and tissue effect," "are substantially equivalent in intended use and/or method of operation," and "demonstrate substantial equivalence ... in terms of safety and effectiveness." The FDA agreed and "determined the [EndoWrist] device" is "substantially equivalent" to the traditional devices, and thus granted EndoWrist 510(k) certifications based on these predicate devices. EndoWrist devices are constructed from traditional medical grade materials, such as stainless steel, composites, and tungsten cables.

27. Intuitive admits that it represented in its 510(k) filing for Endoscopic Intuitive Instruments and Accessories filed on January 19, 1999 that: "[t]he Intuitive Surgical Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited"; "[t]he Intuitive Surgical Endoscopic Instruments and Tools are substantially equivalent in intended use and/or method of operation" to certain predicate devices; with respect to clinical study data, "[a]n extensive prospectively randomized and concurrently controlled clinical study was performed to demonstrate substantial equivalence to the predicate devices cited in terms of safety and effectiveness"; and Intuitive "determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment of the Medical Device Amendment, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act," but otherwise denies the allegations in the second and third sentences of paragraph 27. Intuitive admits that EndoWrists are constructed using medical grade materials, including stainless steel, composites and tungsten cables, but otherwise denies the allegations in the fourth sentence of paragraph 27. Intuitive denies the allegations in the first sentence of paragraph 27.

Paragraph 28: An example of the working end of an EndoWrist Force Bipolar instrument is depicted in the image below: [IMAGE]

28. Intuitive admits that the image in paragraph 28 shows the working end of an EndoWrist Force Bipolar instrument.

Paragraph 29: Many of the EndoWrist instruments have a wide degree of motion at the working tip of the instrument, capable of rotation in multiple planes, and providing an extra level of dexterity that is not available in traditional surgical instruments. The movement at the instrument tip is controlled by tungsten cables located within the EndoWrist. These tungsten cables are actuated by internal pulleys of the EndoWrist that mechanically interface with motors within the robot arms of the da Vinci system. The motors within the robot arms in turn cause the movement of the instrument tip commanded by the surgeon by changing the position of the pulleys and tungsten cables. For the vast majority of EndoWrist instruments, these mechanical components provide for all controls of the instrument tip within the EndoWrist.

29. Intuitive admits that many of the EndoWrists have a wide degree of motion at the working tip of the instrument, capable of rotation in multiple planes, but otherwise denies the allegations in the first sentence of paragraph 29. Intuitive denies the allegations in the second, third, fourth and fifth sentences of paragraph 29.

Paragraph 30: EndoWrists also include an internal memory chip. The internal chip does not control the movement of the EndoWrist instrument tip, but instead stores certain information about the particular EndoWrist, including a model number specific to the type of EndoWrist, a part ID specific to the particular EndoWrist, a chip ID for the chip itself, and a counter value for the particular EndoWrist.

30. Intuitive admits it includes a programmed memory chip in each EndoWrist instrument but otherwise denies the allegations in the first sentence of paragraph 30. Intuitive admits the allegations in the second sentence of paragraph 30.

Paragraph 31: The counter counts the number of times the EndoWrist is attached to a da Vinci robot arm, not an actual measure of usage such as usage time, number of movements, or actuation time. The chip also does not monitor the components of the EndoWrist for conditions that would be indicative of failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables.

31. Intuitive admits that it includes a programmed memory chip in each EndoWrist instrument that, among other functions, counts the number of uses, but otherwise denies the

allegations in the first and second sentences of paragraph 31.

Paragraph 32: The da Vinci robot system queries the memory chip prior to performing any operations with the particular EndoWrist instrument. After a certain number of uses, usually limited to ten, the EndoWrist instrument is rendered non-operational, based solely on the number of times it is attached to a da Vinci robot arm, without any regard to the actual underlying physical condition of the EndoWrist instrument. Without the services of providers such as SIS, the hospital has no choice but to buy a brand-new replacement EndoWrist instrument from Intuitive at full price.

32. Intuitive admits that the da Vinci queries the programmed memory chip in the particular EndoWrist instrument prior to performing any operations, but otherwise denies the allegations in the first sentence of paragraph 32. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists and that the maximum use limit ensures that instruments perform safely and reliably, but otherwise denies the allegations in the second sentence of paragraph 32. Intuitive denies the allegations in the third sentence of paragraph 32.

RESPONSE TO "III. SIS'S ENDOWRIST REPAIR BUSINESS"

Paragraph 33: Services of the type performed by SIS are permitted by the FDA. SIS has properly repaired millions of surgical devices and instruments over its 50 years in business as an independent services operator. After service by SIS, the surgical device or instrument is returned to the customer for its original intended use. Indications for use are not affected, and the surgical device or instrument is returned to its original safety and effectiveness.

33. Intuitive denies the allegations in the first, third and fourth sentence of paragraph 33. Intuitive denies the allegations in the second sentence of paragraph 33 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 34: SIS has created a program for the inspection and repair of EndoWrist instruments. The SIS repair procedures include an initial disassembly and inspection, checking the mechanical operation and integrity of all mechanical components, an electrical integrity check to confirm that electrical insulation, cleaning, sharpening or alignment of the instrument tip, and a series of tests to confirm that all the movements of the instrument tip are within original specifications. SIS also sets the counter to a value corresponding to the initial setting of a new EndoWrist instrument.

34. Intuitive denies the allegations in paragraph 34 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 35: These procedures are similar to procedures that SIS has performed for decades on dozens of types of surgical instruments and medical devices of similar or greater complexity. The materials of the EndoWrist instruments are the same medical grade materials that typically last through hundreds of surgeries and autoclave cycles in other surgical instruments and in medical devices. Particularly after completion of SIS's rigorous set of procedures, the EndoWrist instruments are suitable for many more uses, and at least a number of uses equivalent to Intuitive's originally specified usage limit. In fact, independent testing has shown that EndoWrist instruments serviced by SIS are suitable for 50 or more uses. Nonetheless, SIS returns the counter value to the original value specified by Intuitive.

35. Intuitive denies the allegations in the first, second, fourth and fifth sentences of paragraph 35 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 35.

Paragraph 36: Throughout 2019 and 2020, SIS spoke with numerous hospitals, health care systems, and GPOs regarding its EndoWrist repair and refurbishment offering. These health care providers universally conveyed their frustration with Intuitive and its abusive business practices. In sum, Intuitive's aggressive and ever-changing tactics for extracting an exorbitant per-surgery fee for EndoWrists is financially damaging for hospitals and results in excessive costs for patients.

36. Intuitive denies the allegations in the first and second sentences of paragraph 36 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the third sentence of paragraph 36.

Paragraph 37: Accordingly, SIS entered into service contracts with a number of health care providers, including health care providers in this District and a nationwide GPO. Many of these health care providers were existing SIS customers, such that the ramp up for performing incremental services on EndoWrist instruments would be minimal. SIS was also in late-stage negotiations with numerous additional health care providers, including a number of large health care systems. These agreements and other likely customers would have been worth millions in annual revenue to SIS.

37. Intuitive denies the allegations in paragraph 37 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 38: SIS has the experience, facilities, equipment, and personnel to perform inspection and repair for EndoWrist instruments nationwide. Just based on its initial contracts, SIS was prepared to service at least 1,500 EndoWrists a month. Based on potential agreements and SIS's existing experience and capacity, SIS could have easily ramped up these services to service thousands of additional EndoWrist instruments a month.

38. Intuitive denies the allegations in paragraph 38 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 39: SIS charges approximately 30-45% less per EndoWrist than what a hospital would have to pay to buy a replacement EndoWrist from Intuitive.

39. Intuitive denies the allegations in paragraph 39 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 40: While this is a substantial revenue source for SIS, these revenues pale in comparison to the cost savings to hospitals by using SIS to service EndoWrist instruments rather than throwing away and purchasing new EndoWrist instruments from Intuitive. The vast majority of Intuitive's $2.4 billion in annual instrument sales is for replacement EndoWrists, a large proportion or majority of which would not be needed under SIS's competitive offering. Indeed, even at its inception the cost savings for SIS's EndoWrist repair program were so substantial that one of the health care systems awarded the program its prestigious annual award for health care cost savings.

40. Intuitive denies the allegations in the first and second sentences of paragraph 40. Intuitive denies the allegations in the third sentence of paragraph 40 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 41: Unfortunately for health care providers and patients, Intuitive became aware of SIS's repair program and its relationships with certain health care providers. Intuitive immediately embarked on a scorched-earth pressure campaign to put SIS out of the EndoWrist repair business. And it worked. Faced with coercive threats from the monopoly provider of robotic Surgical Systems to effectively disable their expensive surgical robots, all of the health care providers backed out of SIS's EndoWrist repair program.

41. Intuitive denies the allegations in paragraph 41.

Paragraph 42: In just the last year, health care providers and patients have had to pay hundreds of millions of dollars for unnecessary replacement EndoWrist instruments based on Intuitive's anti-competitive conduct. Intuitive's monopoly power and its anti-competitive use of that power are detailed in the following sections.

42. Intuitive denies the allegations in paragraph 42.

RESPONSE TO "IV. INTUITIVE'S MONOPOLY POWER IN THE RELEVANT MARKETS"

Paragraph 43: There are three relevant markets for purposes of this action: (1) the worldwide and domestic market for surgical robots used in minimally invasive soft tissue surgery; (2) the worldwide and domestic market for repair and maintenance for surgical robots used in minimally invasive soft tissue surgery; and (3) the worldwide and domestic market for replacement or repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery.

43. Intuitive denies the allegations in paragraph 43.

Paragraph 44: Intuitive has monopoly power in (1) the worldwide and domestic market for surgical robots used in minimally invasive soft tissue surgery, (2) the worldwide and domestic market for repair and maintenance for surgical robots used in minimally invasive soft tissue surgery, and (3) the worldwide and domestic market for replacement or repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery, such that Intuitive is able to exclude virtually all competition and charge supra-competitive prices in those markets. With respect to the "repair" aspect of (3), Intuitive has leveraged its monopoly power in robots and instruments, and service of those robots, to prevent any repair services from existing and competing within the EndoWrist instrument aftermarket.

44. Intuitive denies the allegations in paragraph 44.

RESPONSE TO "(1) THE MARKET FOR SURGICAL ROBOTS USED IN MINIMALLY INVASIVE SOFT TISSUE SURGERY"

Paragraph 45: Intuitive's da Vinci surgical robots are primarily used in minimally invasive soft tissue surgery. Initially cleared by the FDA in 1999, the da Vinci robot was the only FDA-cleared surgical robot until 2015. As of 2015, Intuitive had over 3,500 active da Vinci surgical robots at hospitals worldwide.

45. Intuitive admits that the da Vinci was cleared by the FDA for general laparoscopic surgery in 2000 and is primarily used in minimally invasive soft tissue surgery, but otherwise denies the allegations in the first and second sentences of paragraph 45. Intuitive admits that at the end of 2015, it had an installed base of 3,597 da Vincis worldwide, but otherwise denies the allegations in the third sentence of paragraph 45.

Paragraph 46: The market for minimally invasive soft tissue surgery using surgical robots is distinct from minimally invasive procedures performed without surgical robots, primarily due to the advantages that robotic surgery provides and the public perception which comes with those

advantages.

46. Intuitive denies the allegations in paragraph 46.

Paragraph 47: In a traditional laparoscopic surgery performed without a da Vinci robot, a number of trocars are placed through the skin in the target area, and function as placeholders for the surgical instruments or other devices subsequently used to perform the surgery. The surgical instruments and a 2-dimensional camera are then manipulated through a number of small incisions in the target area of the patient, while being manipulated or held by the surgeon(s), nurse(s), surgical assistant(s), and physical supports. More complex laparoscopic surgeries typically require more trocars.

47. Intuitive denies the allegations in paragraph 47 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 48: Like laparoscopic surgery, minimally invasive robotic surgeries are advantageous over traditional open surgeries, in that the surgery is performed through a number of small incisions rather than a large incision of open surgery, resulting in decreased infection rates, faster recovery, and better patient outcomes. But da Vinci robot surgeries also have substantial advantages over laparoscopic surgeries. Rather than physically holding surgical instruments or attaching them to physical supports, the da Vinci robotic surgeries have precision robot arms that accurately hold instrument working tips in position without causing physical strain. The surgeon is seated at an ergonomic console viewing a 3D image of the surgical region. The surgeon is not limited by his or her own physical dexterity in manipulating surgical instruments, but can instead make large scale movements at the console that are translated to precision microscopic movements of surgical instruments. Most of the EndoWrist surgical instruments have a precision-controlled full range of motion about multiple axes at the working end of the instrument, as compared to the limited range of motion and limited precision available with just the human wrist and fingers. Based on the advantages of robotic surgery, some procedures such as prostatectomies are frequently performed by surgeons that exclusively operate using surgical robots.

48. Intuitive admits that minimally invasive robotic surgeries may offer decreased infection rates, faster recovery and better patient outcomes as opposed to open surgery or laparoscopic surgery for certain surgical procedures, but otherwise denies the allegations in the first sentence of paragraph 48 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that the da Vinci may provide surgeons using the system with enhanced visualization, dexterity, precision and ergonomics, that the da Vinci has more “arms” than a human, that EndoWrists can achieve a greater range of

motion than a human hand, that the movements of a surgeon using the da Vinci are scaled, filtered and translated to the system's instruments and that the da Vinci may reduce fatigue during surgical procedures, but otherwise denies the allegations in second, third, fourth, fifth, sixth and seventh sentences of paragraph 48 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 49: Intuitive, many hospitals, many doctors, and many patients believe that minimally invasive robotic surgeries are superior to laparoscopic surgeries. For example, Intuitive advertises that da Vinci surgeries provide "improved outcomes" and "fewer complications" than non-robotic surgery options. A number of clinical studies support the claim that minimally invasive robotic surgeries are more effective and safer than laparoscopic surgery. There is a perception among many doctors and patients that minimally invasive robotic surgeries are safer and more effective than traditional laparoscopic surgeries. Perceptions are such that Intuitive states that "100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci Surgical Systems" and "100% of top-ranked U.S. hospitals own at least one da Vinci System."

49. Intuitive denies the allegations in the first and fourth sentences of paragraph 49 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that there is medical literature that supports the claim that minimally invasive robotic surgeries may offer improved outcomes and fewer complications than alternative healthcare options for certain procedures, but otherwise denies the allegations in the second and third sentences of paragraph 49. Intuitive admits that it has stated that "100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci Surgical Systems" and "100% of top-ranked U.S. hospitals own at least one da Vinci System," but otherwise denies the allegations in the fifth sentence of paragraph 49.

Paragraph 50: There is hardly any cross-elasticity of demand between minimally invasive robotic surgical procedures and laparoscopic procedures. The estimated per-surgery cost of the robot, instruments, equipment, and service for robotic surgery is over three times as much as the comparable costs for laparoscopic surgery, at over $3,500 versus under $1000. Most insurance plans pay the same amount for minimally invasive robotic surgery and laparoscopic surgery, such that patients pay much more out of pocket for minimally invasive robotic surgery and hospitals have lower (and sometimes negative) margins on minimally invasive robotic surgery. Despite the

substantial financial incentives for both patients and hospitals to prefer laparoscopic surgery, the estimated procedure volume for robotic surgery increased from 136,000 in 2008 to 877,000 in 2017 for a compounded annual growth rate of 23%. *Id.* In sum, an increase in the cost of a minimally invasive surgical robot, instruments, and service does not lead doctors or patients to choose laparoscopic or traditional surgery equipment instead, nor would a change in the cost of traditional or laparoscopic equipment affect the market for minimally invasive surgical robots, instruments, and service.

50. Intuitive denies the allegations in the first and sixth sentences of paragraph 50. Intuitive denies the allegations in the second, third, fourth and fifth sentences of paragraph 50 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 51: Indeed, many surgeons specialize in minimally invasive robotic surgeries to the exclusion of laparoscopic surgery. According to Intuitive's annual report for fiscal year 2019, surgeons have performed approximately 1.2 million surgeries with da Vinci robots over the last 20 years. Professional and trade associations such as the Society of Robotic Surgery and the Clinical Robotic Surgery Association are focused on robotic surgery.

51. Intuitive denies the allegations in the first and third sentences of paragraph 51 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the second sentence of paragraph 51.

Paragraph 52: Hospitals that do not have robots such as the da Vinci robots for minimally invasive robotic surgeries are unable to recruit an entire cohort of surgeons and lose out on a large volume of potential surgeries. Because many surgeons perform almost exclusively robotic surgeries, many doctors will go to extraordinary measures to gain access to da Vinci surgical robots, including performing surgery from multiple hospitals and scheduling surgery in the middle of the evening to gain access to a da Vinci robot.

52. Intuitive denies the allegations in paragraph 52 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 53: The market for surgical robots used in minimally invasive soft tissue surgery is distinct from the market(s) for other robotic surgeries. Intuitive is the owner of a large portfolio of patents that have blocked competitors from entering into the surgical robot market for minimally invasive soft tissue surgery. Intuitive also invests heavily to ensure that doctors and medical students are trained to use, and ultimately become dependent on, the da Vinci system.

53. Intuitive denies the allegations in the first sentence of paragraph 53. Intuitive

admits that it owns many patents, but otherwise denies the allegations in the second sentence of paragraph 53. Intuitive admits that it offers technical training relating to the use of the da Vinci to doctors and medical staff, but otherwise denies the allegations in the third sentence of paragraph 53.

Paragraph 54: Most non-Intuitive surgical robots target entirely different types of surgeries than multi-incision minimally invasive soft tissue surgery. Stryker's Mako surgical robots, Smith+Nephew's Cori system, and Zimmer Biomet's Rosa platform are used for orthopedic surgeries such as knee and joint replacements. Siemen's Corindus surgical robots are used for coronary and peripheral vascular procedures. Medrobotics received FDA clearance for its Flex robot for use in natural orifice surgeries. Titan Medical surgical robots is seeking to release a surgical robot limited to single-port surgery. None of these robots compete with Intuitive's da Vinci robots, or in the minimally invasive surgical robot market.

54. Intuitive denies the allegations in the first, second, third, fourth and fifth sentences of paragraph 54 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the sixth sentence of paragraph 54.

Paragraph 55: The few companies that purport to sell robots for minimally invasive surgery have virtually no sales. Medical device company Asensus (formerly known as TransEnterix) received FDA clearance for a minimally invasive surgical robot, the Senhance Surgical Robotic System, in October 2017. However, this robot does not perform numerous surgeries that can be performed with a da Vinci robot, such as cardiothoracic surgery, urologic surgery, and a number of other procedures. In 2019, Asensus shipped 4 Senhance surgical robots worldwide, none of which were in the United States. In contrast, in 2019, Intuitive shipped 1,119 da Vinci surgical robots worldwide, including 728 in the United States. Other medical device companies, such as Medtronic, have plans to enter the minimally invasive robot market, but they have no market share as their products are in the development stage.

55. Intuitive denies the allegations in the first, second, third, fourth and sixth sentences of paragraph 55 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that it reported that it in 2019, it shipped 1,119 da Vincis worldwide, including 728 in the United States, but otherwise denies the allegations in the fifth sentence of paragraph 55.

Paragraph 56: Intuitive's long-time market dominance provides numerous advantages that prevent competition in the market for minimally invasive surgical robots. No other company that sells or has plans to sell a surgical robot has a comparable patent portfolio to the dozens of patents that cover Intuitive's da Vinci robots. Nor do they have the installed base of thousands of robots at hospitals in the United States and worldwide, or the thousands of surgeons who have undergone extensive training specific to da Vinci robots and since performed hundreds of surgeries with da Vinci robots.

56. Intuitive denies the allegations in the first sentence of paragraph 56. Intuitive denies the allegations in the second and third sentences of paragraph 56 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 57: As confirmed by Intuitive's market dominance, it is extremely difficult for competitors to enter the robotic surgery market. FDA clearance takes five to ten years and costs tens or hundreds of millions of dollars from concept to FDA approval, and may require premarket approval, which is much more difficult than 510(k) premarket clearance. Similar regulatory hurdles exist in other jurisdictions, such as the European Union.

57. Intuitive denies the allegations in the first sentence of paragraph 57. Intuitive denies the allegations in the second and third sentences of paragraph 57 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 58: Accordingly, Intuitive has a 99% market share in the worldwide and domestic markets for surgical robots used in minimally invasive soft tissue surgery. Indeed, Intuitive's dominance in the robotic surgery market is so great that even if surgical robots used for entirely different procedures such as orthopedic surgery are considered, recent estimates of Intuitive's overall share of the robotic surgery market range for 77% - 80%.

58. Intuitive denies the allegations in paragraph 58.

Paragraph 59: The installed base of da Vinci robots and the prevalence of da Vinci-trained surgeons precludes new products from gaining market share in the market for minimally invasive surgical robots. Intuitive has an installed base of over 5,500 da Vinci robots worldwide. Switching to a different surgical robot system would be costly for hospitals, requiring them to purchase expensive new robots. A switch would meet substantial resistance from doctors, who would need to abandon the da Vinci surgical methods they have been performing for years (for some, their entire careers), and re-learn how to perform surgeries with different surgical robots. At a 99% market share, including "100% of top-ranked hospitals," the resistance to change does not only affect the few hospitals which do not have da Vinci robots. It affects an enormous portion of the available consumer base.

59. Intuitive denies the allegations in the first, fifth and sixth sentences of paragraph

59. Intuitive admits that it has sold more than 5,500 da Vincis worldwide, but otherwise denies the allegations in second sentence of paragraph 59. Intuitive denies the allegations in the third and fourth sentences of paragraph 59 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 60: Intuitive's market power allows it to obtain supra-competitive margins on its product sales. Although Intuitive does not distinguish between robot and instrument sales for gross margin, its 2019 form 10-K demonstrates over 70% gross margin for robots and instruments. Intuitive's net margin is over 30% based on $1.38 billion in net income on $4.48 billion of total revenue. These margins are significantly higher than margins for typical medical device companies, surgical robotic companies, or other companies that make complex medical equipment.

60. Intuitive denies the allegations in the first sentence of paragraph 60. Intuitive admits that for the year ended December 31, 2019, as noted in Intuitive's 10-K for that year, its product gross profit represented 70.2% of product revenue, and that its net margin was over 30% based on its total revenue of $4,478.5 million, and its net income attributable to Intuitive Surgical, Inc. of $1,381.8 million, but otherwise denies the allegations in the second and third sentences of paragraph 60. Intuitive denies the allegations in the fourth sentence of paragraph 60 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 61: In sum, Intuitive has monopoly power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery. Intuitive is able to and does exclude competition and maintain prices for da Vinci robot systems at supra-competitive levels.

61. Intuitive denies the allegations in paragraph 61.

RESPONSE TO "(2) THE MARKET FOR SERVICE OF ROBOTS USED IN MINIMALLY INVASIVE SOFT TISSUE SURGERY"

Paragraph 62: Intuitive extends its market power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery to the market for repair and support services for their robots.

62. Intuitive denies the allegations in paragraph 62.

Paragraph 63: Once a customer makes the purchase of a DaVinci robot, the only practical service option is service and repair services offered by Intuitive.

63. Intuitive admits that Intuitive performs preventative maintenance and repairs of da Vincis, but otherwise denies the allegations in paragraph 63.

Paragraph 64: Hospitals are dependent on these robot maintenance services for the continued operation of their essential da Vinci robots. The services include "provid[ing] and install[ing]Software upgrades," "replac[ing] defective malfunctioning System parts," and "replac[ing] and install[ing] Software, Hardware, and mechanical parts for safety." Each of these services can only be obtained from Intuitive. And if these services are not provided—e.g., if a malfunctioning part is not replaced or the Software is not up to date—the da Vinci system will display a "NEEDS SERVICE" warning message on the display panel. Doctors will not perform a surgery with a machine indicating that it "NEEDS SERVICE." Nor will patients allow themselves to be operated upon by a machine that "NEEDS SERVICE." Accordingly, when service is needed, the da Vinci robot is effectively rendered useless until service is provided by Intuitive. Hospitals cannot afford to have useless da Vinci robots. Da Vinci robots are large capital investments, and ongoing da Vinci surgeries are necessary to recoup that investment. Functional da Vinci machines are also necessary to maintain the goodwill of the doctors and patients who have scheduled robotic surgeries.

64. Intuitive admits that the da Vinci will display a "NEEDS SERVICE" message on the display panel until needed services—including replacing a malfunctioning part or updating software—are rendered, but otherwise denies the allegations in paragraph 64 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations herein.

Paragraph 65: Intuitive leverages its market power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery, and the market for repair services for their robots, to pressure its customers to use supra-competitively priced replacement EndoWrist parts.

65. Intuitive denies the allegations in paragraph 65.

RESPONSE TO "(3) THE MARKET FOR REPLACEMENT AND REPAIR OF INSTRUMENTS FOR USE IN MINIMALLY INVASIVE SOFT TISSUE SURGERY"

Paragraph 66: Although Intuitive maintains a significant patent portfolio in its surgical robots, any blocking patents for its EndoWrist instruments are long expired. Intuitive maintains a "Patent Notice" web page for its products. Virtually all of the patents covering core structure

and operations for the "EndoWrist" and "Accessories" are expired. The few patents that remain in force are related to specific instrument implementations and could not block a third party from selling competing instruments for use with Intuitive da Vinci robots. Intuitive instead uses technical and contractual means to ensure that only Intuitive-supplied EndoWrists are used with da Vinci robots.

66. Intuitive denies the allegations in the first, third and fourth sentences of paragraph 66 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that it has a "Patent Notice" web page, but otherwise denies the allegations in the second sentence of paragraph 66. Intuitive denies the allegations in the fifth sentence of paragraph 66.

Paragraph 67: One way Intuitive maintains EndoWrist exclusivity is by programing the da Vinci robots to require that any EndoWrist attached has an Intuitive serial number in order to operate. This tactic prevents third parties from manufacturing da Vinci compatible EndoWrists. Intuitive's standard sales contract for da Vinci robots also prohibits customers from using the robot with any surgical instruments not made by or approved by Intuitive. Customers are left with access to only one source for EndoWrists—Intuitive.

67. Intuitive denies the allegations in the first sentence of paragraph 67. Intuitive denies the second and fourth sentences because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive admits that the SLSA for the da Vinci requires customers to use surgical instruments made or approved by Intuitive, but otherwise denies the allegations in the third sentence of paragraph 67.

Paragraph 68: Even if a third party were to successfully create an alternative EndoWrist, the alternative would have to get FDA approval before entering the market. This, in combination with the other mentioned factors, prevents EndoWrist alternatives from becoming available.

68. Intuitive admits that an alternative to EndoWrists from Intuitive for use with the da Vinci would require FDA clearance, but otherwise denies the allegations in paragraph 68.

Paragraph 69: Instruments used for other types of surgical robots, such as orthopedic surgery robots, are not compatible with minimally invasive soft tissue surgery robots. Because they are used in different types of surgeries and do not operate in as small of spaces, they employ different tools and do not include multi-axis end-tool movement control in the same manner as EndoWrists.

69. Intuitive denies the allegations in paragraph 69 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 70: Accordingly, Intuitive has a 99% market share for instruments used with minimally invasive soft tissue surgery robots, because 100% of instruments used with Intuitive da Vinci robots are sold by Intuitive.

70. Intuitive denies the allegations in paragraph 70.

Paragraph 71: Intuitive's market power in instruments used with minimally invasive soft tissue surgery robots is demonstrated by its lucrative revenue and profits in its EndoWrist business. By fiscal year 2019, instrument and accessories (primarily EndoWrists) revenue exceeded $2.4 billion, or more than a $1 billion more than sales of da Vinci systems. Although Intuitive does not break out its gross profit for instruments alone, its gross profit on instruments and da Vinci systems is over 70%. Indeed, the bulk of Intuitive's revenue and profit growth over the last decade has come from its sales of EndoWrist instruments, not robotic systems, as demonstrated from data from Intuitive's 10-Ks from 2001 to 2019, below: [IMAGES]

71. Intuitive denies the allegations in the first sentence of paragraph 71. Intuitive admits that for the year ended December 31, 2019, as noted in Intuitive's 10-K for that year, Intuitive reported $2,408.2 million in revenue for instruments and accessories and $1.346 billion from da Vincis, but otherwise denies the allegations in the second sentence of paragraph 71. Intuitive admits that for the year ended December 31, 2019, as noted in Intuitive's 10-K for that year, its product gross profit "increased 21% to $2.6 billion, representing 70.2% of product revenue," but otherwise denies the allegations in the third sentence of paragraph 71. Intuitive admits that over the last decade, more of its revenue and profit growth have come from sales of EndoWrists than da Vincis, but otherwise denies the allegations in the fourth sentence of paragraph 71.

Paragraph 72: Indeed, while Intuitive's sales of robots were stagnant from 2012 – 2017, Intuitive's EndoWrist sales increased by over $730 million dollars during that time period. As is described in the following paragraphs, the bulk of Intuitive's EndoWrist windfall revenue, and thus the bulk of its corporate revenue and profitability, is based on its anti-competitive conduct that requires hospitals to purchase replacement EndoWrists rather than repairing EndoWrists that are capable of many more uses at a significantly reduced price.

72. Intuitive admits that its EndoWrist sales increased between 2012 and 2017 by over $730 million dollars, but otherwise denies the allegations in paragraph 72.

Paragraph 73: The vast majority of Intuitive's EndoWrist revenue and profit, and thus its overall revenue and profit, comes from replacement EndoWrists. The da Vinci robots are typically in service for years, if not a decade or more, and EndoWrists provide a recurring revenue stream. In the words of Intuitive's Form 10-Ks from the early 2000's, EndoWrist instruments include a counter that allows it to "sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis."

73. Intuitive admits that its 10-K for the year ended December 31, 2000 stated that Intuitive "can sell the instruments for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure basis or per-hour basis," and that EndoWrists provide a recurring revenue, but otherwise denies the allegations in paragraph 73.

Paragraph 74: Specifically, the EndoWrist chip includes a counter that counts the number of times the EndoWrist is attached to a da Vinci robot arm. This is not an actual measure of usage such as usage time, number of movements, or actuation time. The chip does not monitor the components of the EndoWrist for conditions that would be indicative of failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables. The counter is set to a variety of values for different instruments such as 10, 12, 15, 18, 30, and 100. For virtually all EndoWrists instruments, the counter is set to the lower part of that range, and the vast majority of EndoWrist instruments have their counter set at 10 attachments.

74. Intuitive admits that it includes a programmed memory chip in each EndoWrist that, among other functions, counts the number of uses, but otherwise denies the allegations in the first sentence of paragraph 74. Intuitive admits that it has conducted rigorous testing and identified a maximum use limit for EndoWrists, which varies based on instrument, and that the maximum use limit ensures that instruments perform safely and reliably. Intuitive denies the remaining allegations in paragraph 74.

Paragraph 75: Intuitive has unilaterally changed counter values for types of EndoWrist instruments and its pricing for those instruments. Intuitive has also unilaterally changed the instructions for use (IFU) for EndoWrist instruments to force early replacement, even if the counter value has not expired. For example, Intuitive issued an IFU for EndoWrist instruments setting a

maximum number of autoclave cycles. Because of the way that da Vinci surgeries are prepped and performed, EndoWrist instruments often have to undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes substantially increase the per-surgery cost of EndoWrist instruments to hospitals, and Intuitive's supra-competitive EndoWrist profits, without prior notice to hospitals. When hospitals make the substantial capital and contractual commitment to purchase a da Vinci robot, they are unaware of these additional costs and lack information to predict Intuitive's unilateral changes.

75. Intuitive admits that it has changed the use limits and prices of certain EndoWrists and the instructions for use, but otherwise denies the allegations in the first sentence of paragraph 75. Intuitive denies the allegations in the second, sixth and seventh sentences of paragraph 75. Intuitive admits that it has issued an IFU for EndoWrists setting a maximum number of autoclave cycles, as required by the FDA, but otherwise denies the allegations in the third sentence of paragraph 75. Intuitive denies the allegations in the fourth and fifth sentences of paragraph 75 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 76: Intuitive does not provide hospitals any option for repair of the EndoWrist instrument after the counter has expired. Instead, once the counter has expired the hospital must purchase a new EndoWrist at a cost ranging from $2,250 - $3,750, without regard to whether the EndoWrist instrument was actually used in surgery or the extent of such use.

76. Intuitive admits that it does not provide "repairs" of EndoWrists, but otherwise denies the allegations in paragraph 76.

Paragraph 77: At least SIS has attempted to enter the market for repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery, and specifically, for repair of EndoWrists. On information and belief, other companies similar to SIS have attempted to enter this market.

77. Intuitive denies the allegations in paragraph 77.

Paragraph 78: As described previously herein, SIS employs meticulous procedures to inspect, and as necessary, repair EndoWrist instruments. Once the EndoWrist is returned to original specifications, SIS sets the counter to the same value originally programmed by Intuitive. Based on its 50 years of expertise in surgical equipment repair and the demonstrated safety and efficacy of its EndoWrist repair process, SIS entered into contracts and was in negotiations for contracts

with hospitals, health care providers, and GPOs representing thousands of EndoWrists a year and tens of millions in revenue, just in the first year.

78. Intuitive denies the allegations in paragraph 78 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein.

Paragraph 79: An EndoWrist serviced by SIS would cost only 55-70% of the cost of buying a replacement EndoWrist from Intuitive, and would be equally safe for the same number of subsequent uses.

79. Intuitive denies the allegations in paragraph 79.

Paragraph 80: Although SIS's business was poised to grow substantially year-over-year, SIS's expected sales of tens of millions of dollars in 2020 would still amount to less than 1% market share for replacement and repair of EndoWrists. SIS had obtained and was in the process of repairing EndoWrists from some of these initial customers, when Intuitive embarked on a scorched-earth campaign to put SIS out of the EndoWrist repair business. SIS repaired Endo Wrists that were successfully used in surgeries without any problems or incidents.

80. Intuitive denies the allegations in the first and third sentences of paragraph 80 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations therein. Intuitive denies the allegations in the second sentence of paragraph 80.

Paragraph 81: In view of Intuitive's 99% market share for minimally invasive soft tissue surgery robots, 100% market share for the servicing and support of those robots, and the 100% market share of instruments used with Intuitive da Vinci robots, Intuitive has leveraged its monopoly power in all these markets and engaged in other anti-competitive acts to prevent repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery. Intuitive's wrongful acts are described in the following section.

81. Intuitive denies the allegations in paragraph 81.

RESPONSE TO "V. INTUITIVE'S MONOPOLIST TACTICS AND ANTI-COMPETITIVE ACTS"

Paragraph 82: Intuitive has engaged in an anticompetitive course of conduct consisting of several primary anticompetitive practices. Intuitive has harmed competition through and by these practices.

82. Intuitive denies the allegations in paragraph 82.

Paragraph 83: One of Intuitive's anticompetitive practices involves requiring its customers for the da Vinci robotic surgical system to agree to numerous restrictive terms that allow Intuitive to

subsequently disable and effectively render the da Vinci robots inoperable at some later time (for example, by refusing to service the robots).

83. Intuitive denies the allegations in paragraph 83.

Paragraph 84: A second anticompetitive practice involves unilaterally modifying the terms for EndoWrists once a hospital has invested in a da Vinci robot, such as unilateral changes in pricing, use limits, and restrictive instructions for use.

84. Intuitive denies the allegations in paragraph 84.

Paragraph 85: A third anticompetitive practice employed by Intuitive involves refusing to provide hospitals, health care systems, and GPOs with an option to have their previously used EndoWrist instruments repaired after the internal counter has expired.

85. Intuitive denies the allegations in paragraph 85.

Paragraph 86: A fourth anticompetitive practice used by Intuitive involves requiring customers who purchase its da Vinci robotic systems to agree that they will not permit the repair or refurbishment of any EndoWrist instruments by a third party. If a customer violates this prohibition, Intuitive has threatened to void the warranties on the da Vinci robotic system, completely terminate the agreement with that customer, refuse to provide further service and support for the robotic system, and even render the surgical robot inoperable.

86. Intuitive denies the allegations in the first sentence of paragraph 86. Intuitive admits that it contacted certain customers in response to the customers' use of third-party remanufacturers and, among other things such as expressing safety concerns relating to the use of adulterated instruments, reminded customers of contractual obligations under the SLSA, but otherwise denies the allegations in the second sentence of paragraph 86.

Paragraph 87: An effect of Intuitive's anticompetitive conduct is to generate and sustain unreasonably high, supra-competitive prices for aftermarket EndoWrist instruments.

87. Intuitive denies the allegations in paragraph 87.

Paragraph 88: Intuitive's anticompetitive conduct effectively forecloses customers who have purchased da Vinci robotic surgery systems from having access to competitive sources of aftermarket EndoWrist instruments in violation of the Sherman Act Sections 1 and 2.

88. Intuitive denies the allegations in paragraph 88.

Paragraph 89: Through Intuitive's coercive practices directed at da Vinci customers, it

foreclosed rivals from supplying customers with aftermarket EndoWrist instruments through repair and refurbishment services. In so doing, Intuitive maintains its monopoly power in the EndoWrist instrument aftermarket which it has used to sustain unreasonably high replacement rates and supra-competitive prices.

89. Intuitive denies the allegations in paragraph 89.

Paragraph 90: Intuitive's practices have the practical effect of preventing a buyer of a da Vinci robotic system from using the products and services of a potential competitor in the EndoWrist instrument aftermarket. Intuitive's practices have prevented SIS's entry as a rival into the EndoWrist instrument aftermarket.

90. Intuitive denies the allegations in paragraph 90.

Paragraph 91: On information and belief, Intuitive became aware that SIS was providing owners of da Vinci robots with repaired EndoWrist instruments in late 2019.

91. Intuitive denies the allegations in paragraph 91.

Paragraph 92: Between late 2019 to early 2020, Intuitive sent letters to and had in-person conversations with SIS's customers or potential customers, knowing that they were under contract or in contractual negotiations for repaired EndoWrists. As a result of the threats and misleading statements in those letters and conversations, all of SIS's EndoWrists customers backed out of their contracts or did not sign contracts under negotiation, effectively eviscerating SIS's EndoWrist repair business.

92. Intuitive admits that it contacted certain customers in response to the customers' use of third-party remanufacturers, but otherwise denies the allegations in paragraph 92.

Paragraph 93: In letters to SIS customers and potential customers, Intuitive claimed that repairs might lead to "degraded performance," including "unintuitive motion," "insufficient grip force," "dull or damaged scissor blades," and "worn/damaged cables." To the contrary, under SIS procedures all of these aspects of EndoWrist performance, and numerous others, are inspected in detail and repaired as necessary to meet Intuitive's original equipment specifications.

93. Intuitive admits that it sent a letter to certain customers stating, inter alia, that "[a]ll Intuitive Surgical products are rigorously tested, reviewed and cleared by regulatory authorities to achieve a targeted level of safety, precisions, and dexterity over all programmed instruments uses by the original manufacturer. Gradual degradation occurs both from use in surgery as well as repeated cleaning and sterilization required between uses." Intuitive admits

that the letter also stated that "[e]xamples of degraded performance may include but are not limited to: [u]nintuitive motion (i.e., instruments do not track well with master manipulators; [u]nexpected motions or stalls); [i]nsufficient grip force; dull or damaged scissor blades; [w]orn/damaged cables," but otherwise denies the allegations in paragraph 93.

Paragraph 94: Intuitive also alleged that "third- party manufacturers or refurbishers may use non-validated or incompatible cleaning agents and/or disinfection/sterilization processes" or "may damage the instrument's internal mechanisms that interface with the robotic system and allow Intuitive to monitor the device." To the contrary, with years of experience working with millions of diverse devices that require sterilization procedures, SIS processes do not employ "incompatible cleaning agents and/or disinfection/sterilization processes." Nor would SIS return a device to the customer that was damaged or could not interface properly with Intuitive's robotic system.

94. Intuitive admits that it has sent letters to certain customers stating, inter alia, that "[t]hird party remanufacturers or refurbishers might use non validated or incompatible cleaning agents" and "third party remanufacturers or refurbishers may damage the instrument's internal mechanisms that interface with the robotic system and allow Intuitive to monitor the device," but otherwise denies the allegations in the first sentence of paragraph 94. Intuitive denies the allegations in the second and third sentences of paragraph 94 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations.

Paragraph 95: In sum, if Intuitive had only alleged that SIS's services might potentially cause these issues, SIS's customers and potential customers would have had no worry whatsoever doing EndoWrist business with SIS. SIS has a sterling reputation of repairing surgical devices such as EndoWrists, and robust processes specific to the EndoWrists.

95. Intuitive denies the allegations in paragraph 95 because it is without knowledge or information sufficient to form a belief as to the truth of the allegations.

Paragraph 96: Intuitive instead asserted numerous threats and misleading statements by letter and in private conversations to prevent SIS from performing its repair services, and to maintain its monopoly profits in EndoWrists.

96. Intuitive denies the allegations in paragraph 96.

Paragraph 97: A first set of Intuitive's misleading statements made by letter relates to FDA

clearances. Couched in terms of "might prevent such products from performing" such that FDA and other regulations "may not apply," Intuitive states without any basis that "the hospital has no way to know whether the refurbished instrument meets the rigorous specifications" of Intuitive and the FDA. Intuitive also states that "any modification to allow for use of a da Vinci product beyond its useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use" in violation in 21 U.S.C. § 351.

97. Intuitive admits that it has sent a letter to certain customers stating, inter alia, that "[r]efurbishing activities performed by an unauthorized third party violate the U.S. Federal Food, Drug, and Cosmetic Act ('FDC Act') and the regulations promulgated and enforced thereunder by the FDA when such activities do not bring products to established specifications or when such activities change intended uses. Deviation from these specifications might prevent such products from performing properly, thereby subjecting patients to significant risk. By using a third party remanufacturer or refurbisher, the hospital has no way to know whether the refurbished instrument meets the rigorous specifications as established by Intuitive Surgical and cleared by the FDA or other regulators." Intuitive admits that the letter states that "any modification to allow for use of a da Vinci product beyond its useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use. Engaging in such activities without first obtaining a new clearance to do so misbrands the product under 21 U.S.C. § 351." Intuitive otherwise denies the allegations in paragraph 97.

Paragraph 98: The components of the EndoWrists are medical grade parts with a useful life of dozens if not hundreds of uses. They will operate within specification, particularly when properly inspected and repaired as is performed by SIS. Intuitive's allegation appears to be that use of EndoWrists beyond the counter limit is a violation of Intuitive's FDA clearances. Based on FDA clearances that have been identified for EndoWrists to date, this assertion is incorrect. At most, Intuitive merely mentions in its FDA applications that its devices have usage limits. Available 510(k) summaries are silent on usage limits, and have no prohibitions whatsoever on repair.

98. Intuitive admits that it believes any modification to allow for use of a da Vinci product beyond its useful life exceeds the scope of the original clearance by expanding the FDA

cleared indications for use, and that engaging in such activities without first obtaining a new clearance to do so misbrands the product under 21 U.S.C. § 351, but otherwise denies the allegations in paragraph 98.

Paragraph 99: A second misleading statement made by letter relates to unspecified "intellectual property rights in the da Vinci systems and its instruments" that "Intuitive believes it has[.]" SIS merely repairs EndoWrists, which according to Intuitive's own Patent Notice webpage do not have any relevant patent rights that would cover SIS's services. Nor are there any other intellectual property rights that SIS's services would call into question.

99. Intuitive avers that no response to paragraph 99 is necessary in light of the Court's November 23, 2021 Order dismissing SIS's claims arising out of the alleged statement described in the paragraph. (ECF No. 70, at 12.) To the extent that any response is necessary, Intuitive admits that it has sent a letter to certain customers stating that "Intuitive believes that it has important intellectual property rights in the da Vinci system and its instruments," but otherwise denies the allegations in paragraph 99.

Paragraph 100: Intuitive's letters also inform SIS customers of certain "terms of [the customer's agreements with Intuitive] that you might wish to consider." According to Intuitive, such terms include prohibitions on "repair, refurbishment, or reconditioning" and another asserts that the hospital's "license [for an EndoWrist] expires once an Instrument or Accessory is used up to its maximum number of uses[.]" Another term referenced by Intuitive states that the hospital will not "permit any third party to, modify, disassemble, [or] reverse engineer . . . the System or Instrument or Accessories." Failure to comply with the latter term results in termination of the hospital's "Agreement immediately upon written notice, and any warranties applicable to the system will become void."

100. Intuitive admits that it has sent letters to certain customers concerning their use of unauthorized services on instruments that stated, inter alia, "here are terms of your SLSA that you might wish to consider," but otherwise denies the allegations in the first sentence of paragraph 100. Intuitive admits that this letter quoted provisions of the SLSA that state that "'Instruments and Accessories are subject to a limited license'" which prohibits "'repair, refurbishment, or reconditioning not approved by Intuitive'" and "'expires once an Instrument or

Accessory is used up to its maximum number of uses specified in the Documentation accompanying the Instrument or Accessory,'" but otherwise denies the allegations in the second sentence of paragraph 100. Intuitive admits that this letter quoted another provision of the SLSA in which customers agree not to "'permit any third party to, modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories'" and that if the customer does not comply with that requirement, "'Intuitive may terminate this Agreement immediately upon written notice, and any warranties applicable to the system will become void,'" but otherwise denies the allegations in the third and fourth sentences of paragraph 100.

Paragraph 101: Notably, the Agreement that Intuitive is referring to and the remedies it is threatening are for the "System," *i.e.*, the surgical robot. These terms constitute attempts by Intuitive to constrain its customers with illegal exclusive dealing agreements, and constitute illegal tying of EndoWrists and EndoWrist related services to the original purchase of the da Vinci robot. These provisions are particularly egregious in view of Intuitive's market power in the market for minimally invasive surgical robots. The effectiveness of its exclusive dealing and tying requirements are proven by Intuitive's market power in the market for replacement instruments for minimally invasive surgical robots, and its ability to completely foreclose the market for repair of such instruments.

101. Intuitive denies the allegations in paragraph 101.

Paragraph 102: Intuitive's letters make its threats explicit—if the hospital uses repaired instruments, Intuitive will render its surgical robot inoperable. Not only will Intuitive seek damages or indemnity from its customer, but if Intuitive discovers "Systems being used with instruments by an unauthorized third party, Intuitive may no longer accept your service calls for such Systems." Because Intuitive also refuses to allow any competition in the market for service of its robots, and refuses to make error codes and other critical information available to third parties, failure to provide such service will render a robot that originally cost well over a million dollars inoperable. Many hospitals have multiple such robots that would thus be rendered inoperable.

102. Intuitive admits that it has sent a letter to certain customers stating, inter alia, that with regard to "[s]ystems being used with instruments by an unauthorized third party, Intuitive may no longer accept your service calls for such Systems," but otherwise denies the allegations in paragraph 102.

Paragraph 103: Intuitive's letter continues, stating that "[s]hould Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System." Again, the threat is explicit—if the hospital uses refurbished instruments, Intuitive will render its surgical robot inoperable.

103. Intuitive admits that it has sent letters to certain customers stating, inter alia, that "[s]hould Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System," but otherwise denies the allegations in paragraph 103.

Paragraph 104: In private conversations, Intuitive representatives have made this threat even more explicit. In response to one hospital's use of third-party repair services, an Intuitive representative stated that Intuitive would turn the surgical robot into a "paperweight."

104. Intuitive denies the allegations in paragraph 104.

Paragraph 105: These threats provide further evidence of Intuitive improperly leveraging its monopoly power in the relevant markets to maintain its lucrative EndoWrist sales and margins, and to prevent the development of a repair market at all costs.

105. Intuitive denies the allegations in paragraph 105.

Paragraph 106: Intuitive has also engaged in other anticompetitive conduct to protect and expand its EndoWrist monopoly. As described herein, Intuitive unilaterally changes counter values and pricing for EndoWrist instruments, and has unilaterally changed IFUs to require replacement of EndoWrist instruments after an unreasonably low number of autoclave cycles.

106. Intuitive denies the allegations in paragraph 106.

Paragraph 107: For its most recent Xi generation of da Vinci robots and EndoWrist instruments, Intuitive has made an inordinate investment in encryption and other countermeasures of the internal EndoWrist chip. There is no technical or safety justification for these excessive efforts, except to prevent third parties such as SIS from accessing the counter. Specifically, it would not be possible to operate an EndoWrist instrument with a da Vinci robot if other values of the EndoWrist chip such as the EndoWrist serial number were modified. Intuitive's sole purpose is to prevent competition in repair services and to unjustifiably protect its supra-competitive EndoWrist profits. Intuitive's anti-competitive conduct operates to the

detriment of patients, hospitals, and SIS, by using unjustified technical measures to prevent an EndoWrist repair market from existing for the Xi EndoWrists.

107. Intuitive denies the allegations in paragraph 107.

Paragraph 108: In order to protect its EndoWrist monopoly pricing, Intuitive has taken steps to force customers to switch from da Vinci robots (typically "S" and "Si" robots) for which EndoWrist repair is possible to Xi da Vinci robots for which EndoWrist repair is not currently possible. For example, Intuitive has announced that as of 2023 it intends to stop selling S and Si EndoWrist instruments, and to discontinue providing service and technical support for da Vinci S and Si robots. By withdrawing service and technical support, Intuitive is effectively rendering these robots inoperable.

108. Intuitive admits that it is gradually phasing out S and Si instruments, as well as service and technical support for da Vinci S and Si systems, but otherwise denies the allegations in paragraph 108.

Paragraph 109: Intuitive has offered favorable terms and pricing to induce customers to move from S and Si da Vinci robots to Xi robots, knowing that it can recoup lost revenue many times over by preventing repair of Xi EndoWrist instruments.

109. Intuitive denies the allegations in paragraph 109.

Paragraph 110: In sum, Intuitive has gone to extraordinary efforts to leverage its monopoly power in robots for use in minimally invasive soft tissue surgery, the repair and support of those robotic systems, and its monopoly power in instruments for use with such robots to foreclose aftermarket repair of those instruments by any competitors. This costs hospitals and patients at least 30-45% per instrument (which savings would increase over time) or hundreds of millions of dollars a year in a $2.4 billion market, without any safety or technical justification.

110. Intuitive denies the allegations in paragraph 110.

RESPONSE TO "COUNT I – TYING"

Paragraph 111: SIS incorporates all of the above paragraphs as though fully set forth herein.

111. To the extent SIS re-alleges all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 112: Intuitive has dominant economic power in the worldwide and domestic markets for surgical robots for minimally invasive soft tissue surgery, for servicing, support and repair of those robots, and with respect to instruments for use with such robots. Intuitive has used this economic power to coerce its customers into buying EndoWrists from Intuitive rather than allowing

the option of repairing EndoWrists through experienced service organizations such as SIS. Intuitive has conditioned the sale and servicing of its da Vinci surgical robots on customers buying replacement EndoWrists from Intuitive instead of permitting the use of EndoWrists that customers previously purchased but later had repaired, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This tying arrangement has anticompetitive effects in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery, which involves a substantial amount of interstate commerce.

112. Intuitive denies the allegations in paragraph 112.

Paragraph 113: As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

113. Intuitive denies the allegations in paragraph 113.

RESPONSE TO "COUNT II – EXCLUSIVE DEALING"

Paragraph 114: SIS incorporates all of the above paragraphs as though fully set forth herein.

114. To the extent SIS re-alleges all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 115: Intuitive has taken measures and entered into agreements with its customers that require the customers to replace their EndoWrist instruments on an exclusive basis with new Intuitive EndoWrists, thus foreclosing competition in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This exclusive dealing has anticompetitive effects in the worldwide and domestic markets for repair and replacement of these instruments, which involves a substantial amount of interstate commerce.

115. Intuitive denies the allegations in paragraph 115.

Paragraph 116: As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

116. Intuitive denies the allegations in paragraph 116.

RESPONSE TO "COUNT III – MONOPOLIZATION"

Paragraph 117: SIS incorporates all of the above paragraphs as though fully set forth herein.

117. To the extent SIS re-alleges all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 118: Intuitive has willfully obtained and maintains monopoly power in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 99% market share by excluding competitors. Intuitive's exclusionary tactics include tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots, prohibiting customers from having their EndoWrists repaired, sending cease and desist letters when customers attempt to have EndoWrists repaired, and employing countermeasures to the Xi instrument usage counter to prevent any modification of the usage counter.

118. Intuitive denies the allegations in paragraph 118.

Paragraph 119: As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

119. Intuitive denies the allegations in paragraph 119.

RESPONSE TO "COUNT IV – ATTEMPTED MONOPOLIZATION"

Paragraph 120: SIS incorporates all of the above paragraphs as though fully set forth herein.

120. To the extent SIS re-alleges all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 121: Intuitive has acted with the clear intent to obtain monopoly power in the worldwide and domestic markets for the repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive has engaged in anticompetitive conduct including tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots, prohibiting customers from having their EndoWrists repaired, sending cease and desist letters when customers attempt to have EndoWrists repaired, and employing countermeasures to the Xi instrument usage counter to prevent modification of the usage counter. Intuitive has at least a 99% market share and has a high probability of successfully monopolizing the market.

121. Intuitive denies the allegations in paragraph 121.

[Misnumbered] Paragraph 70: As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

70. Intuitive denies the allegations in misnumbered paragraph 70.

RESPONSE TO "COUNT V – UNFAIR TRADE PRACTICES – VIOLATION OF LANHAM ACT"

Paragraph 122: SIS incorporates all of the above paragraphs as though fully set forth herein.

122. To the extent SIS re-alleges all of the paragraphs above, Intuitive reasserts its answers to those paragraphs.

Paragraph 123: Intuitive, in connection with the sale of its EndoWrist instruments, asserted false or misleading descriptions of facts or representations in its correspondence with its and SIS's customers and such misrepresentations were likely to cause consumer confusion or inaccurately describe the nature, characteristics, or qualities of its and SIS's commercial activities in violation of Section 43 of the Lanham Act, 15 U.S.C. § 1125.

123. Intuitive denies the allegations in paragraph 123.

Paragraph 124: Intuitive has at least misrepresented that SIS's services are contrary to FDA approvals of the EndoWrist products and are in violation of intellectual property rights. Intuitive sent such correspondence to multiple SIS customers and potential customers. Intuitive made such statements knowingly, willfully, and/or recklessly that such statements were misleading. These misleading statements affected the purchasing decisions of such customers.

124. Intuitive denies the allegations in paragraph 124, and further avers that SIS's claims arising out of the alleged statement described therein have been dismissed by the Court. (ECF No. 70, at 12.)

Paragraph 125: Intuitive's misrepresentations were made to SIS's customers, and upon information and belief, a significant number of Intuitive customers that have, or had, Intuitive Si robots.

125. Intuitive denies the allegations in paragraph 125.

Paragraph 126: SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries flow from that which

makes Intuitive's conduct unlawful under the Lanham Act. SIS is entitled to all relief available for such misleading statements, including but not limited to injunctive relief, disgorgement of Intuitive's ill-gotten profits, recovery of SIS's damages, attorneys' fees, the costs of this action, and treble damages under the Lanham Act, 15 U.S.C. § 1117(a).

126. Intuitive denies the allegations in paragraph 126.

RESPONSE TO "PRAYER FOR RELIEF"

Responding to the unnumbered paragraph and each of its subparts under the heading "PRAYER FOR RELIEF," Intuitive denies that SIS is entitled to any damages, costs of suit, attorney's fees, injunctive relief or any other form of relief.

RESPONSE TO "DEMAND FOR JURY"

Intuitive admits that SIS demands trial of all claims by jury to the extent authorized by law.

PREAMBLE TO AFFIRMATIVE DEFENSE

Intuitive reserves the right to rely upon any of the following or additional defenses to claims asserted by SIS to the extent that such defenses are supported by information developed through discovery or evidence at trial and thus reserves the right to amend its Answer and Affirmative Defense. By asserting the following affirmative defense, Intuitive does not allege or admit it has the burden of proof or the burden of persuasion with respect to any matter:

FIRST DEFENSE

SIS's claims are barred, in whole or in part, by the doctrine of unclean hands because SIS has acted contrary to applicable FDA regulations and/or engaged in other misconduct, including tortious interference with Intuitive's contracts and business relationships.

DEFENDANT'S COUNTERCLAIMS

Intuitive Surgical, Inc. ("Intuitive"), by its undersigned counsel, counterclaims against Surgical Instrument Service Company, Inc. ("SIS"), and alleges, upon personal knowledge as to itself and its own acts and upon information and belief as to all other matters, as follows:

INTRODUCTION

1. This lawsuit concerns SIS's misinformation campaign to deceive Intuitive customers into believing that the unauthorized modification and remanufacturing of Intuitive's EndoWrist surgical instruments ("EndoWrists") facilitated by SIS is safe, cost-effective, actually conducted by SIS and consistent with both EndoWrists' design specifications and FDA clearances. In reality, the service marketed by SIS as EndoWrist "repair" is none of those things. To the contrary, the "repair" involves another party breaking into EndoWrists and inserting an unauthorized circuit board called the "Interceptor" to override the instruments' safe, prescribed and FDA-cleared use limits. The resulting inferior and unlawful products—still bearing Intuitive's trademarks—carry significant risk not only to Intuitive customers but also to the patients on whom they are used to operate.

2. The result of decades of investment and innovation, Intuitive offers surgical systems for use in conducting minimally invasive procedures, including the highly touted da Vinci Surgical System ("da Vinci") and its related instruments and accessories. Intuitive's multi-functional instruments with EndoWrist technology feature wristed joints for natural dexterity, giving surgeons an expanded range of motion and increased precision.

3. Consistent with industry standards and best practices, and as required by the FDA, Intuitive has conducted rigorous testing and identified maximum use limits for EndoWrists. The maximum use limits, built into the EndoWrists, ensures that instruments perform safely and

reliably. Once the limit is reached, the instrument will no longer be operational, requiring that it be replaced to avoid putting patients at risk.

4. EndoWrists are cleared by the FDA to be marketed and sold pursuant to the premarket clearance process set forth in Section 510(k) of the Food, Drug, and Cosmetic Act. The 510(k) process required Intuitive to submit to the FDA extensive data and testing results validating the safety and dependability of EndoWrists within the prescribed use limits. FDA cleared EndoWrists as limited use or "resposable" instruments with use limits, and any modification of EndoWrists by a third party to increase the use limits requires a new 510(k) clearance. SIS did not seek—and the FDA did not provide—510(k) clearance for EndoWrists that are modified so that they could be used ***beyond*** the number of uses that had been validated as safe and reliable.

5. In light of safety and reliability concerns, among others, customers agree in their contracts with Intuitive that (i) they will not use Intuitive instruments after the maximum use limit is reached, and (ii) unauthorized parties are prohibited from modifying or altering the instruments.

6. Despite being well aware of the prohibitions in Intuitive's contracts, SIS has solicited Intuitive customers to retain it to "repair" EndoWrists and override their use counters. Unbeknownst to the customers, once retained, SIS sends instruments to a third party, Rebotix Repair LLC ("Rebotix"), that breaks into the EndoWrists and implants the unauthorized "Interceptor" circuit board. This unauthorized process results in "manufactured" or "remanufactured" instruments that include new materials inconsistent with the instruments' design and functional requirements. These added materials have never been tested or validated by Intuitive and, upon information and belief, have not been properly tested or validated by

Rebotix or SIS in accordance with regulatory requirements. Rebotix then returns the adulterated instruments back to SIS, which in turn sends them back to its customers for use in surgical procedures.

7. SIS does not inform Intuitive customers of the true nature of SIS's (and Rebotix's) unauthorized operations, let alone the substantial medical, financial and legal risks that customers face if they secure EndoWrist "repairs" through SIS.

8. SIS's success thus depends on its ability to deceive Intuitive customers. To that end, marketing materials and communications disseminated by SIS are rife with false and misleading statements, all as part of a coordinated effort to bolster and legitimize unlawful EndoWrist remanufacturing operations.

9. SIS's willfully deceptive marketing claims are of several stripes. Many specifically concern the nature of the offered service, deceiving customers into believing that EndoWrist use limits can be extended in a way that is safe, effective and reliable and that conforms to regulatory requirements. For example:

a. SIS states that it is "repairing" EndoWrists and does not describe the actual, substantial modifications being made to the instruments. *See, e.g.*, Ex. 1, Ex. 2, Ex. 3. Contrary to a mere "repair," the Interceptor process is not a tune-up or calibration, but rather ***changes*** EndoWrists in fundamental (and risky) ways.

b. SIS purports to offer a "complete evaluation, repair, and test" of EndoWrists, further conveying a false message that the instruments are broken or defective when they reach their use limit. *See, e.g.*, Ex. 2. But SIS knows that the use limits are a ***feature***, not a bug, of EndoWrists because they ensure proper and safe operation.

c. SIS claims that serviced EndoWrists will "meet the quality and functional requirements of a new device" (*see, e.g.*, Ex. 3), but SIS does not have access to Intuitive's design history and other internal files to identify the "quality and functional requirements" of new EndoWrists.

d. SIS similarly claims that a "repaired" EndoWrist "is an original da Vinci manufactured device that has been repaired to original specifications" (*see, e.g.*, Ex. 1), but SIS does not know the instruments' "original specifications" and is aware that

overriding prescribed use limits would be inconsistent with any such specifications.

e. SIS misrepresents Intuitive's justifications for use limits and Intuitive's testing and safety protocols, as well as the safety of SIS's service.

10. The foregoing deceptive messages are compounded by SIS falsely representing to customers that ***it*** performs the "repairs" and has tested the reliability of the use-extended EndoWrists. SIS thus leverages its brand and purported long history of experience servicing surgical instruments while obscuring the fact that EndoWrist "repair" is actually done by Rebotix. *See, e.g.*, Ex. 2, Ex. 3. In fact, SIS has never conducted a repair of an EndoWrist for a customer or conducted any testing of the "repaired" instruments.

11. Based on the false premise that the service is merely a "repair" of EndoWrists, SIS also misinforms customers that "repaired" instruments do not require 510(k) premarket clearance by the FDA. *See, e.g.*, Ex. 3. Relatedly, SIS misinforms customers that the "repair" service does not change the intended use, method of use, functionality or performance of EndoWrists. Both sets of representations are not true, and SIS made the statements either with knowledge of their falsity or, at minimum, without conducting any independent or meaningful investigation as to whether clearance was required. SIS has further misinformed customers about the nature and scope of Intuitive's 510(k) clearance for EndoWrists, such as misinforming customers that the FDA only regulates single-use surgical instruments.

12. Yet another category of SIS's false advertising is its touting and purported validation of cost savings for customers who use the "repair" service instead of purchasing new EndoWrists. For example, SIS advertises that its service offers significant savings for customers. Lacking a legitimate basis to make such claims, SIS fails to inform customers and/or affirmatively misrepresents the financial and legal consequences for customers that use the unauthorized services, such as the voiding of customers' warranties and jeopardizing of their

service contracts with Intuitive.

13. SIS also has leveled false accusations against Intuitive, including a baseless and inflammatory charge that the use limitations built into EndoWrists are "arbitrary." *See, e.g.*, Ex. 2. SIS knows, or should know, however, that the use limits are critical for patient safety, designed in compliance with FDA regulations, requirements and publications, consistent with applicable industry standards as well as EndoWrist labeling and amply supported and validated by scientific testing.

14. SIS's communications similarly have falsely suggested that the "repair" service was authorized by, approved by or affiliated with Intuitive, including through misleading references to Intuitive trademarks and describing SIS as an "authorized" EndoWrist "service" company.

15. SIS's deceptive practices are not strictly limited to its false advertising. Despite being qualitatively different from and inferior to originally manufactured EndoWrists, "repaired" instruments with the unauthorized "Interceptor" still bear Intuitive's trademarks. As such, surgeons and others encountering the "repaired" EndoWrists are led to believe that those instruments still are genuine Intuitive products. That deception is furthered by SIS's communications stating that "[a] repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications." Ex. 1.

16. All of the foregoing deceptive practices are part and parcel of SIS's false pitch that: (i) it can and does "repair" EndoWrists in a manner that saves large sums of money without any downside or risk; (ii) such "repair" service is authorized by Intuitive and does not require FDA 510(k) clearance; and (iii) Intuitive's safety and other requirements need not be adhered to

or trusted. The dangers of such an inaccurate campaign to customers and their patients are self-evident, and SIS bears liability for these reckless communications.

PARTIES

17. Intuitive is a Delaware corporation with its principal place of business at 1266 Kifer Road, Sunnyvale, California. Among other services, Intuitive manufactures and sells surgical systems, along with related instruments and accessories, to hospitals and surgical centers world-wide.

18. Surgical Instrument Service Company, Inc. is an Illinois corporation with a principal place of business at 151 N. Brandon Drive, Glendale Heights, Illinois. SIS purports to offer repair and replacement services for Intuitive's EndoWrists, including but not limited to customers in California.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over Intuitive's federal claims under 28 U.S.C. § 1331 and § 1332. The federal claims arise under the Lanham Act, 15 U.S.C. § 1125. This Court has supplemental subject matter jurisdiction over Intuitive's state-law claims under 28 U.S.C. § 1367(a).

20. This Court has personal jurisdiction over SIS, and venue is proper in the Northern District of California pursuant to 28 U.S.C. § 1391(b) and (c), as SIS has appeared in this action and initiated this action by filing claims against Intuitive in this District.

GENERAL ALLEGATIONS

I. Intuitive's da Vinci Surgical Systems and EndoWrist Precision Instruments

21. Intuitive designs, manufactures and markets da Vincis and related instruments and accessories, which have become widely known as an advanced generation of surgery. Da Vincis

combine the benefits of minimally-invasive surgery for patients with the ease of use, precision and dexterity of open surgery for surgeons.

22. A da Vinci consists of a surgeon's console, a patient-side cart and a high-performance vision system. Da Vinci technology translates a surgeon's natural hand movements, which are performed on instrument controls at the console, into corresponding micro-movements of instruments positioned inside the patient through small incisions or ports. The da Vinci provides operating surgeons with intuitive control, range of motion, fine tissue manipulation capability and three-dimensional, high-definition vision, while simultaneously allowing surgeons to work through small ports.

23. Through its extensive efforts and investments in research and development, as well as through strategic alliances with other medical and technology companies, Intuitive has developed and commercialized four generational platforms of da Vinci and continues to innovate in order to help surgeons improve surgical outcomes.

24. In addition to the primary surgical platforms, Intuitive develops, manufactures and sells compatible instruments and accessories customized for various surgical procedures, such as forceps, scissors, electrocautery tools and scalpels.

25. Most of these instruments incorporate EndoWrist technology, which feature wristed joints for natural dexterity. Inspired by the human hand, EndoWrists enable surgeons to orient the instruments carefully relative to the tissue and suture with precision, just as they can in open surgery. EndoWrists' internal cables provide maximum responsiveness, allowing for rapid and precise suturing, dissection and tissue manipulation**.**

26. Because of the innovations and benefits that they provide, da Vincis and EndoWrists have successfully enabled surgeons to perform a wide range of surgical procedures

across a variety of specialties. That success has made Intuitive's offerings a highly desirable, competitive alternative to other surgical modalities, such as open and laparoscopic surgery.

II. Use Limits Ensure EndoWrists Meet The Highest Quality and Safety Standards and Are Compliant With Applicable State, Federal and International Requirements and Guidelines

27. Intuitive goes to great lengths to ensure that its various products are safe, effective and reliable. Through its dedicated engineers, Intuitive subjects its products to extensive testing to ensure its products are safe, reliable and efficacious.

28. Among other steps taken to ensure that EndoWrists meet exacting performance specifications, most are designed with a use life of a defined number of procedures. A programmed memory chip inside each such instrument performs several functions that help determine how the da Vinci and EndoWrists work together, including by not allowing instruments to be used for more than the prescribed and appropriate number of procedures.

29. The use limits for EndoWrists are determined through a rigorous process involving substantial scientific testing and analysis. For example, instruments are subject to testing protocols that: (i) expose them to mechanical and electrical stress representative of intended use, taking into account procedure variances; and (ii) put them through typical installation, cleaning and sterilization cycles to simulate real-life uses in the surgical field as nearly as possible. Analyzing the data from its various tests, Intuitive also applies complex statistical models to identify risks and confirm the number of times that each instrument can safely and reliably be used.

30. Intuitive's incorporation of use limits into EndoWrists and other products is important as a best practice, critical to regulatory compliance and consistent with 510(k) clearance for previous iterations of the EndoWrist.

31. Many of Intuitive's products and operations are subject to regulation in each of the countries and regions where Intuitive markets and sells products. Intuitive therefore is careful to stay up to date on the requirements of a large and growing body of international standards, which govern the design, manufacture, sourcing, testing, certification, packaging, installation, use and disposal of Intuitive products.

32. In the United States, for example, Intuitive submits many of its systems, instruments and accessories to the U.S. Food and Drug Administration ("FDA") for premarket clearance.

33. Under the Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide a reasonable assurance of safety and effectiveness. Intuitive's current products, including EndoWrists, are Class II medical devices, which are subject to general controls and typically require premarket demonstration of adherence to FDA performance standards or other special controls in order to obtain clearance. Premarket review and clearance are accomplished through the 510(k) premarket notification process.

34. Critically, through its regulations, requirements and publications, the FDA mandates that in order for 510(k) clearance to be issued, the EndoWrist's maximum use limits must be determined and disclosed. Accordingly, when Intuitive builds use limits into EndoWrists, it is both adhering to best practices and taking the steps necessary to comply with federal (and other) requirements. It is further complying with FDA's prior 510(k) clearances of EndoWrists as limited use devices with use limits built in.

35. Even after a medical device like an EndoWrist receives initial 510(k) clearance

from the FDA, any ***modification*** to the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a ***new*** 510(k) clearance, or could even require a premarket application ("PMA") approval. *See* 21 C.F.R. § 807.81(a)(3). The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) clearance or PMA in the first instance, but the FDA may review any such determination. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular modification, the FDA may retroactively require the manufacturer to do so, and under certain circumstances may require the manufacturer to cease marketing and/or recall the modified device until clearance or approval is obtained.

36. The FDA recently stated to Intuitive that extending the number of lives on EndoWrists with use limits is inconsistent with the cleared labels and requires a separate 510(k) submission that includes "[b]ench validation data or scientific justification" in order "to demonstrate that the instruments maintain adequate performance (as defined in your existing instrument validation protocols) after the maximum number of uses and reprocessing cycles." Exs. 6, 7.

37. Any company that ***manufactures*** a non-exempt device, including a finished device component for sale to an end user, must obtain 510(k) clearance. *See* 21 U.S.C, §§ 321(h); 807.3(d)(3); 807.81(a)(2); 807.20(a), (a)(6).

38. Further, any company that ***remanufactures*** devices or instruments as that term is defined by the FDA must obtain 510(k) clearance. *See* 21 C.F.R. § 807.81(a)(3). Per FDA regulations, a "remanufacturer" is "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's

performance or safety specifications, or intended use." *See* 21 C.F.R. § 820.3(w).

III. Intuitive's Commitment to Product Safety, Quality and Efficacy By Prohibiting Unauthorized Maintenance and Support Services

39. Given the surgical uses for which Intuitive's products are designed, proper maintenance of those products is essential. Intuitive customers therefore have access to an expansive infrastructure of specialists and engineers around the world who can offer a full complement of round-the-clock support and service for the da Vincis. That infrastructure includes a network of field service engineers across the United States, Europe and Asia, as well as distributors and service providers around the globe with whom Intuitive maintains relationships.

40. Intuitive ensures that any in-house technicians or authorized third-party technicians that are part of Intuitive's service and support teams have the specialized training and experience necessary to safely and reliably work on the highly technical da Vincis. This training continues throughout the course of the technicians' careers servicing the da Vinci so that they are fully up-to-date on the technology.

41. Maintenance or modification of Intuitive devices by unauthorized and/or unqualified individuals, however, could lead to adverse outcomes and carry additional risk to surgical patients and to Intuitive customers that Intuitive would be unable to mitigate. For example: (i) non-validated reprocessing methods, and unknown handling and transit conditions have the potential to damage instruments; (ii) handling and product modification can impact traceability and monitoring of the device by Intuitive, including Intuitive's ability to update customers about important developments like recalls; and (iii) using unauthorized channels for acquisition or maintenance of products may violate a given hospital's or health care facility's internal policies and impact the validity of patient consents.

42. For these reasons and others, Intuitive carefully restricts who is permitted to perform maintenance and support services on its products and prohibits unauthorized parties from doing so.

43. In that regard, Intuitive customers enter into binding Sales, License, and Service Agreements ("SLSA") governing their acquisition and use of Intuitive devices. In those Agreements, the customer unequivocally agrees that, *inter alia*, it "will not, ***nor will Customer permit any third party to***, ***modify***, disassemble, reverse engineer, ***alter***, or misuse" the Da Vinci Surgical System or instruments (such as EndoWrist) and accessories. SLSA § 3.4 (emphasis added).

44. If a third party does modify, alter, or otherwise manipulate Intuitive devices, thus violating the above contractual provision, "any warranties applicable to the System will become void" and Intuitive may terminate the SLSA immediately upon written notice. *Id.* Relatedly, if a customer "has used the System with surgical instruments or accessories that are not Instruments or Accessories [i.e., those made or approved by Intuitive for use with the System]," then the system warranty "is void with respect to any claims." SLSA §§ 2, 10.

45. The SLSA also includes an express acknowledgment by Intuitive customers that they may not use instruments after they have exceeded the use limits, or if those instruments have been subject to any servicing or modification not authorized by Intuitive:

> Instruments and Accessories are subject to a limited license to use those instruments and Accessories with, and prepare those Instruments and Accessories for use with, the System. ***Any other use is prohibited,*** whether before or after the Instrument or Accessory's license expiration, ***including repair, refurbishment, or reconditioning not approved by Intuitive***. ***This license expires once an instrument or Accessory is used up to its maximum number of uses*** specified in the Documentation accompanying the Instrument or Accessory.

SLSA § 8 (emphasis added); *see also id.* § 3.4 (requiring proper use of the da Vinci system

consistent with the attached documentation, including the user manual).

IV. SIS's Unauthorized Facilitation of Overriding EndoWrist Use Limits By A Third Party, Rebotix Repair LLC

46. SIS characterizes itself as a medical and surgical device servicing company that has been a "trusted partner for over 50 years." *See* http://sis-usa.com/. In its marketing, SIS asserts that "SIS technicians are among the most highly-skilled and experienced in the industry," with a "majority" that are "pioneers in improved repair techniques." http://sis-usa.com/services/. Central to SIS's branding is not only its purported expertise—e.g., that it can "extend the useful life of your critical instruments"—but also the notion that it is trustworthy. SIS states, for example, that it has "no competing agendas" and "we always speak honestly with our customers." *Id.*

47. SIS markets its services to customers throughout the United States, including customers in the State of California.

48. SIS learned of a process by which another party, Rebotix Repair LLC ("Rebotix"), was manufacturing EndoWrists with finished device components (i.e., the Interceptor) and/or remanufacturing EndoWrists in order to override their use limits. Unconcerned with serious safety implications for surgical patients, or legal and financial consequences for Intuitive customers, Rebotix developed its "Interceptor" process to disable memory chips in EndoWrists. That process involves breaking into the instruments, discarding original instrument circuit boards, soldering the Intuitive memory chips onto unauthorized circuit boards and installing those adulterated circuit boards back into the instruments. In short, Rebotix inserts its own technology to override a fundamental feature of EndoWrists, significantly changing their intended use and their performance and safety specifications.

49. Notwithstanding the fact that Rebotix's modifications of EndoWrists are

substantial, and that its activity renders Rebotix a "manufacturer" or "remanufacturer" within the context of applicable FDA regulations (*see supra* ¶¶ 35-38), Rebotix never received 510(k) clearance from the FDA for its operations or for the marketing and sale of EndoWrists with overridden use counters. Upon information and belief, SIS knew that Rebotix never received 510(k) clearance and was aware of Rebotix's prior communications with the FDA in which Rebotix failed to obtain any such clearance.

50. Indeed, Rebotix's failure to receive 510(k) clearance for its operations is directly contrary to the FDA's directive to Rebotix that the Interceptor "repair" process ***requires*** 510(k) clearance. For example, in a letter to Rebotix in 2018, the FDA indicated to Rebotix that its Interceptor process required 510(k) clearance. Specifically, the FDA stated, "for the reusable Endowrist Instruments, if the use-life counter is reset of extended past the number of available use lives, then the device specification are changed." Intuitive's Motion to Stay Exhibit, REBOTIX166917, (ECF No. 46-2). On this basis, the FDA indicated that Rebotix would be "subject to premarket notification (510(k)) requirements." *Id*.

51. Seeking to piggyback on Intuitive's success and expand its own business, SIS entered into a business relationship with Rebotix whereby SIS effectively functions as a distributor. Upon information and belief, SIS markets and sells EndoWrist "repairs" to hospitals and collects devices from the hospitals to deliver them to Rebotix, which then conducts the "repairs." SIS pays Rebotix a "distributor price" for each "repair" and charges SIS customers a higher retail price for the "repaired" device.

52. SIS entered into the relationship with Rebotix and has marketed and sold the "repair" service to customers despite being fully aware that EndoWrists should not be used for more than the prescribed and appropriate number of procedures, and that Intuitive's customers

agree in their service contracts that unauthorized parties should not service or modify instruments.

53. SIS also is aware that Rebotix had not obtained 510(k) clearance from the FDA to market or sell the "repaired" EndoWrists.

54. SIS has never conducted an EndoWrist "repair" for a customer. Instead, it only provides EndoWrists to Rebotix and then reaps the premium that it charges its customers.

V. SIS's Deceptive Marketing and Conduct

55. SIS's EndoWrist-related business is supported by a misinformation campaign targeted at Intuitive customers. The overarching goal of the campaign is to persuade EndoWrist purchasers into believing that the "repairs" SIS coordinated are actually provided by SIS, legitimate, cost-effective, safe and without any downside or risk. In reality, SIS's (and Rebotix's) service is none of those things.

56. SIS's campaign of deception spans several different kinds of false and misleading marketing claims.

57. Much of SIS's efforts at deception concern misrepresenting the nature, efficacy and safety of its service. As set forth above, the Interceptor process overhauls EndoWrists, forcing them to operate beyond their safe, reliable and FDA-cleared use lives. Yet SIS falsely markets the service as safe, effective and reliable, and conceals from the public that the service requires breaking into Intuitive instruments to make modifications such as inserting an unauthorized circuit board.

58. For example, SIS markets the service as a "repair" or "complete evaluation, repair, and test" of EndoWrists, inaccurately conveying to customers that the service is simply a tune up or other routine step to bring the instruments back to their original condition. *See* Exs. 1,

2.

59. Suggesting that EndoWrists are "repaired" not only mischaracterizes the nature of SIS's (more accurately, Rebotix's) operations, but further conveys the false message that instruments that have reached their use limits are broken, defective or otherwise in need of fixing. SIS knows, however, that there is nothing broken about an EndoWrist that cannot exceed its predetermined use limit; to the contrary, that the instrument can no longer be used is a fully intended—and critically important—safety feature.

60. SIS furthers the deception about what the "repair" actually entails by falsely touting that a "repaired" EndoWrist (i) "meet[s] the quality and functional requirements of a new device" (Ex. 3) and (ii) "has been repaired to original specifications" (Ex. 1). These fictions are reiterated even in SIS's Complaint in this litigation. SIS Compl. ¶ 8 ("SIS's services ensure that the inspected or repaired EndoWrists meet all original specifications").

61. These claims deceive customers in at least two ways. ***First***, it is not true that the adulterated EndoWrists retain "original specifications" or "meet the quality and functional requirements of a new device." SIS and Rebotix do not have the capability to provide customers with modified EndoWrists equivalent to the quality and functional requirements of new, out-of-the-box, EndoWrists manufactured by Intuitive. At its core, the remanufactured product is qualitatively different from—and does not maintain the original specifications of—an out-of-the-box EndoWrist (e.g., it incorporates the unauthorized "Interceptor" and exceeds the instrument's prescribed use limits, which themselves are specifications for the instruments). ***Second***, SIS misrepresents that it has taken the steps necessary to sufficiently validate its claim that the "requirements" of a "new device" have been met—e.g., conducting or relying on reliable scientific testing and analysis. SIS plainly had not done so, nor has SIS ever had access to the

Intuitive internal files that would specify the "quality and functional requirements" of new EndoWrists.

62. SIS compounds the deceptiveness of the "repair" messaging by falsely conveying to customers that it is ***SIS*** that actually has developed and performs the "complete evaluation, repair and test" of EndoWrists. Seeking to leverage its reputation and "50-year history of performing repairs," SIS does not disclose that SIS does not perform the EndoWrist "repair" itself or did not perform any of the testing that purportedly supports the safety and reliability of the EndoWrist "repair" process. In fact, SIS has utilized ***Rebotix*'s** deceptive communications and simply re-branded them as SIS's. *Compare* Ex. 2, *with* Ex. 4; *compare* Ex. 3, *with* Ex. 5.

63. Evidence that customers actually have been deceived by the foregoing false messaging already exists on the public record. In a separate federal litigation concerning EndoWrists, a putative class of Intuitive customers have alleged that SIS "has already serviced and repaired EndoWrists." *In re: Da Vinci Surgical Robot Antitrust Litigation*, Case 3:21-cv-03825-VC, ECF No. 52, "Larkin Amended Complaint," at ¶ 124.

64. Certain other deceptive marketing claims by SIS concern the legality and legitimacy of the remanufacturing services.

65. To mollify concerns that customers would have about subjecting surgical instruments to unauthorized "repair" services, and further underscore the false message that the service is safe, effective and reliable, SIS falsely informed customers that the EndoWrist services do not require FDA certification or clearance. *See*, *e.g.*, Ex. 3. But that is not true. As set forth above, any company that ***manufactures*** a non-exempt finished device component for sale to an end user or ***remanufactures*** devices or instruments—including engaging in any "act to a finished device that significantly changes the finished device's performance or safety specifications, ***or***

intended use" (21 C.F.R. § 807.81(a)(3))—must obtain 510(k) clearance. *See* 21 C.F.R. § 820.3(w) (emphasis added).

66. Relatedly, SIS falsely informs customers that its "repair" process does not change the intended use, method of use, functionality or performance of EndoWrists. By inserting the Interceptor to override use limits, SIS changes the intended use of EndoWrists, which requires conformance to the prescribed and FDA-cleared use limits. SIS's "repair" process was also not adequately tested to ensure safe and effective use beyond FDA-cleared limits. Accordingly, the "repair" process results in EndoWrists whose functionality and performance have been significantly changed.

67. Upon information and belief, SIS knew all along that 510(k) clearance was required (but had not been obtained). At minimum, SIS did not conduct any independent or meaningful investigation to determine whether additional clearance is necessary.

68. Yet another category of SIS's false advertising is its claims that using the "repair" service would result in substantial cost-savings and financial benefits for Intuitive customers. For example, SIS has claimed that it can provide an Intuitive customer with significant savings, and the public record indicates that customers did in fact believe similar claims of savings of as much as 55-70% by using SIS rather than purchasing replacement EndoWrists from Intuitive. *See* Larkin Amended Complaint ¶¶ 7, 155. This, too, is deceptive because SIS has no legitimate basis or support to make such claims.

69. SIS's marketing and communications also deceive customers by intentionally obscuring and omitting the negative consequences for customers that retain SIS, including that SIS's unauthorized alterations could void customers' warranties. SIS fails to inform customers that its unauthorized services could subject customers to contract and warranty ramifications

under their SLSAs with Intuitive by virtue of using unauthorized service technicians.

70. SIS also has leveled false accusations against Intuitive and attacked Intuitive's credibility and trustworthiness. For example, SIS baselessly asserts that the EndoWrists' use limits are "arbitrary." *See, e.g.*, Ex. 2. As detailed above (*supra* at ¶¶ 3, 4, 29), nothing could be further from the truth; the use limits were set after rigorous analysis, are determined pursuant to FDA law and regulations and industry standards and are an essential component of ensuring patient health and safety.

71. Finally, SIS misleads customers into believing that its service is authorized, approved, or endorsed by Intuitive. SIS's marketing materials frequently depict Intuitive's trademarks, including marks protected by incontestable federal registrations such as "EndoWrist" (U.S. Reg. No. 2,591,824) and "da Vinci" (U.S. Reg. No. 2,628,871). In addition, SIS has referred to itself as an "authorized" EndoWrist "service" company.

72. Even beyond its false advertising, SIS deceives customers by misrepresenting "repaired" instruments as genuine, Intuitive-manufactured EndoWrists. As detailed above, the Interceptor process fundamentally alters EndoWrists, rendering them qualitatively different from, and inferior to, EndoWrists originally manufactured and sold by Intuitive (and cleared by the FDA). Yet the "repaired" instruments appear outwardly identical to Intuitive's EndoWrists and still bear Intuitive's trademarks—including trademarks for which Intuitive holds incontestable federal registrations, such as "EndoWrist" (U.S. Reg. No. 2,591,824) and "Intuitive Surgical" (U.S. Reg. No. 2,364,862). As such, surgeons and other downstream users or recipients of the "repaired" EndoWrists——including anyone who experienced inconsistencies or failures with the adulterated instruments—are likely to confuse the adulterated instruments with Intuitive-manufactured products.

73. SIS's communications furthered this deception by utilizing Intuitive's registered trademarks on its marketing materials and by expressly telling its customers that "[a] repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications." (Ex. 1.)

VI. Through its Unfair Business Practices, SIS Has Knowingly Interfered With Intuitive's Business and Contractual Relationships With its Customers.

74. As noted above (*supra* at ¶¶ 43-45) Intuitive SLSAs include express acknowledgments by customers that (i) they will not use Intuitive instruments after the maximum use limit is reached; (ii) their licenses to use instruments (such as EndoWrists) expire once maximum use limits are reached; and (iii) they will not use unauthorized components or permit third parties to modify or alter the instruments, and doing so will void Intuitive's warranties and permit Intuitive to terminate the service contracts.

75. SIS had knowledge of the SLSAs and the terms thereof, including the foregoing provisions.

76. Notwithstanding such knowledge, SIS has induced Intuitive customers to breach the SLSAs to their detriment and utilize SIS's (and, unbeknownst to the customers, Rebotix's) services, resulting in EndoWrist use beyond their intended, prescribed, and FDA-cleared use limits.

77. SIS's interference with the relationship between Intuitive and its customers goes beyond facilitating the breach of the SLSA. For example, SIS has sought to disrupt that relationship by misinforming customers that Intuitive is dishonest and engages in unethical or unlawful practices, such as by setting "arbitrary" EndoWrist use limits. SIS further sold a service to customers that required 510(k) clearance under FDA rules and regulations, despite not having such clearance. Thus, SIS's actions are not the reflection of legitimate competition but

rather an improper means to induce customers into breaching their contracts with Intuitive.

VIII. The Substantial and Irreparable Harm to Intuitive and Its Customers

78. SIS's deceptive conduct and interference with Intuitive's contractual relationships has harmed Intuitive and its customers in a number of ways, including, but not limited to, the following:

79. ***First***, SIS's unlawful conduct has deprived Intuitive of business. For example, customers who would have ordered replacement EndoWrists when it is time to do so are instead turning to SIS's so-called "repair" services.

80. ***Second***, Intuitive's reputation and goodwill has been damaged by SIS's direct attacks on Intuitive's honesty and integrity. By baselessly asserting that the EndoWrist's use limits are "arbitrary" and financially motivated, SIS tells customers that Intuitive should not be trusted, and that its important guidance on proper instrument use need not be followed.

81. ***Third***, to the extent that "repaired" EndoWrists do not function properly during surgery, it jeopardizes the public trust and confidence that Intuitive has inspired among its customers' patients.

82. ***Fourth***, customers themselves have been harmed in numerous ways by SIS's unlawful conduct, including by (i) receiving a qualitatively different and inferior product than that which they had bargained for; (ii) not receiving the cost-savings actually promised by SIS; (iii) having their service contracts and/or warranties with Intuitive voided or otherwise jeopardized; (iv) having their ability to raise concerns about adulterated (and misbranded) devices with the proper parties, including the FDA, inhibited; and (v) not having the ability to look up reports concerning those devices on the FDA's website or other databases.

83. While certain of the aforementioned categories of harm have injured Intuitive in a

way that can be compensated in an amount to be determined at trial, much of it—such as the injury to Intuitive's reputation and customer relationships—is not readily calculable and may not be entirely redressed through monetary damages. Such irreparable harm can only be fully remedied through injunctive relief.

COUNT ONE

(Unfair Competition and False Advertising – Lanham Act, 15 U.S.C. § 1125)

84. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

85. In its marketing materials and communications disseminated to potential and actual customers, SIS has made numerous false and misleading statements, including but not limited to the statements more specifically enumerated above that misrepresent: (i) the nature, efficacy, and/or safety of the service SIS coordinates (e.g., by referring to those services as mere "repairs" or similar terms); (ii) that "repaired" EndoWrists meet applicable quality and functional requirements; (iii) that devices "serviced" through SIS had been repaired to meet "original specifications" of EndoWrists and are safe to use; (iv) that SIS itself developed, has tested and conducts the "repairs;" (v) that the "repair" and/or resulting instruments do not require clearance by the FDA (and/or that SIS actually engaged in an independent or meaningful analysis of whether such clearance is necessary); (vi) that use of the service will result in substantial cost-savings; (vii) that use of the service does not carry any adverse financial, legal or other consequences (e.g., voiding Intuitive customers' warranties); (viii) that use limits built into EndoWrists are "arbitrary" or Intuitive otherwise is not trustworthy; and (ix) that SIS and/or the "repair" service is authorized, approved, or endorsed by Intuitive.

86. SIS's deceptive conduct also includes returning qualitatively different and inferior

instruments to customers but passing off those products as genuine Intuitive EndoWrists. In that regard, "repaired" instruments still bear Intuitive's trademarks, including trademarks protected by incontestable federal registrations. The resulting confusion as to the source or affiliation of the "repaired" instruments is exacerbated by SIS's communications that also leverage Intuitive's trademarks and misinform customers that "a repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications."

87. SIS's deceptive statements and conduct have deceived and confused, and/or have the capacity to deceive and confuse, a substantial segment of Intuitive's current and potential consumers.

88. SIS's deceptive statements and conduct are material and likely to influence consumer purchasing decisions.

89. Both Intuitive's EndoWrists and SIS's services (and the "repaired" instruments) are advertised, offered for sale and sold in interstate commerce.

90. SIS's deceptive statements and conduct are willful and made with the knowledge that they are untruthful and/or unlawful.

91. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

COUNT TWO

(Unfair Competition Law – CA. Stat. § 17200)

92. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

93. SIS's conduct detailed above constitutes unlawful, unfair and deceptive acts or practices in the conduct of trade or commerce.

94. SIS willfully used or practiced these acts in violation of California's unfair competition statute, Section 17200, and SIS knew or should have known that its acts were unlawful and would damage Intuitive and injure consumers by its deception

95. SIS's conduct has resulted in substantial harm to competition.

96. Intuitive, which has a principal place of business in California, has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

COUNT THREE

(False Advertising – CA. Stat. § 17500)

97. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

98. SIS intended for consumers in California to purchase EndoWrist "repairs" from it.

99. SIS's publicly disseminated marketing and advertising materials include numerous statements detailed above SIS knew or should have known through the exercise of reasonable care were both untrue and misleading.

100. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

COUNT FOUR

(Common Law Unfair Competition)

101. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

102. SIS is a competitor of Intuitive and has engaged in the above-detailed deceptive and fraudulent conduct with the intent to confuse and deceive the public into using its service and purchasing "repaired" EndoWrists.

103. SIS's conduct has caused deception and confusion among consumers.

104. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

COUNT FIVE

(Tortious Interference With Contract)

105. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

106. At all relevant times, Intuitive has had contractual relationships with its customers, including through the SLSAs, which contain limitations concerning the modification or alteration of Intuitive EndoWrists. SIS was at all times aware of these contractual relationships and has undertaken intentional acts to disrupt them and/or induce Intuitive customers to breach them.

107. SIS's actions have resulted in actual breach or disruption of contractual relationships between Intuitive and its customers.

108. There is no legal justification for SIS's actions, which have been motivated purely

by its own greed and subjected Intuitive patients, Intuitive customers and Intuitive itself to substantial harm.

109. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

JURY TRIAL

110. Intuitive requests a jury trial as to all issues so triable.

PRAYER FOR RELIEF

111. Intuitive respectfully requests this Court enter judgment in favor of Intuitive and against SIS including an Order granting Intuitive the following relief:

a. Compensatory damages on all applicable causes of action alleged herein;

b. Actual costs, expenses and attorneys' fees incurred in this lawsuit;

c. All exemplary, enhanced and punitive damages;

d. Pre-judgment and post-judgment interest;

e. Preliminary and permanent injunctive relief; and

f. Such other and further relief as the Court shall deem just and proper.

DATED: December 14, 2021

/s/ Allen Ruby
ALLEN RUBY (SBN 47109)
allen@allenruby.com
ALLEN RUBY, ATTORNEY AT LAW
15559 Union Ave. #138
Los Gatos, CA 95032
Telephone: (408) 477-9690

KAREN HOFFMAN LENT (*Pro Hac Vice*)
karen.lent@skadden.com
MICHAEL H. MENITOVE (*Pro Hac Vice*)
michael.menitove@skadden.com
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Telephone: (212) 735-3000
Facsimile: (212) 735-2040

MICHAEL S. BAILEY (*Pro Hac Vice*)
michael.bailey@skadden.com
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Telephone: (202) 371-7000
Facsimile: (202) 393-5760

Attorneys for Defendant
INTUITIVE SURGICAL, INC.